

**Nebraska Department of Health and Human Services
Regulation and Licensure**

Request for Proposals

**Office of Family Health
Reproductive Health Program**

**TITLE X FAMILY PLANNING SERVICES
STATE OF NEBRASKA**

Date of Issuance: August 8, 2006

Proposals Due: October 9, 2006, 5:00 p.m. CT

Issuing Office: Office of Family Health
Reproductive Health Program
Nebraska Department of Health and Human Services
Regulation and Licensure
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**TITLE X FAMILY PLANNING SERVICES
STATE OF NEBRASKA
REQUEST FOR PROPOSALS
TABLE OF CONTENTS**

<u>SECTION I. OVERVIEW</u>	1
<u>SECTION II. SCOPE OF WORK</u>	7
<u>SECTION III. PROPOSAL REQUIREMENTS</u>	12
<u>ATTACHMENT 1</u>	19
<u>ATTACHMENT 2</u>	23
<u>ATTACHMENT 3</u>	36
<u>ATTACHMENT 4</u>	65
<u>ATTACHMENT 5</u>	69
<u>ATTACHMENT 6</u>	71
<u>EXHIBIT 1</u>	77
<u>EXHIBIT 2</u>	78
<u>EXHIBIT 3</u>	81
<u>ATTACHMENT 7</u>	94
<u>ATTACHMENT 8</u>	95
<u>ATTACHMENT 9</u>	96
<u>ATTACHMENT 10</u>	98
<u>ATTACHMENT 11</u>	99

SECTION I. OVERVIEW

A. Purpose of Request for Proposals

This Request for Proposals (RFP), issued by the Nebraska Department of Health and Human Services Regulation and Licensure (Department), Office of Family Health (Office), Reproductive Health Program (Program) seeks proposals from qualified entities that will provide family planning services in Nebraska. Such services will be provided in accordance with federal Title X Family Planning Services statutes, regulations and guidelines, other applicable federal statutes, regulations and circulars and Nebraska State Laws and administrative guidance.

Through this RFP, the Department will award a total of approximately \$1.5 million in Title X grant funds and \$150,000 in Title V Maternal and Child Health Services funds per 12 month period and adjusted for an initial 18 month period. The amount of funding per project will be dependent on several factors, including the number and quality of proposals received, the geographic areas proposed, the specific work plans and budgets of individual proposals, and proportionate allocation of funds among delegates through use of a funding formula. The Title X Family Planning funding formula considers base costs, number of sites, and numbers and proportion of low-income patients served. The Title V Maternal and Child Health Services funds are allocated proportionately based on each delegates % of the total Title X grant funds awarded.

The initial funding period is for eighteen months and will begin January 1, 2007 and continue through June 30, 2008 and the available funds are to be estimated accordingly. Annual, non-competing continuation awards will be made for one year periods for each of the subsequent two years, July 1, 2008 through June 30, 2010, for project(s) demonstrating satisfactory performance and submitting acceptable continuation proposals. Awards made during the initial and subsequent periods are dependent on the availability of federal funds.

The intention is to fund project(s) that demonstrate capacity and experience in providing family planning and other related reproductive health services to low income persons and education on reproductive health topics to community groups.

B. Background

The Nebraska Department of Health and Human Services Regulation and Licensure is the recipient of federal Title X Family Planning Services grant funds. In addition, the Department is the recipient of Title V Maternal and Child Health Services funds, with a portion then allocated to the Reproductive Health Program. The Department in turn subgrants these funds to community-based providers or “delegates” to provide reproductive health services. These delegates are required to prioritize services to low-income persons. The delegates provide education, counseling and comprehensive medical and social services necessary to enable individuals to freely determine the number and spacing of their children, and by doing so, help reduce maternal and infant mortality, promote the health of mothers and children, prevent child abuse, prevent adolescent pregnancy, reduce unintended pregnancies, and reduce rates of sexually transmitted diseases.

Reproductive health services must be provided at no charge to individuals at or below 100% of the federal poverty guidelines. All Title X Family Planning services must be provided on a proportional sliding fee scale to those individuals from 101% up to 250% of the federal poverty guidelines. The lowest segment of the scale would optimally be set at 20% of full fee but be no more than 33%. Potential delegates will be given preference if, historically or through projection, 40% or more of their clients are \leq 150% of federal poverty guidelines.

Reproductive health services to be provided include: physical assessment, breast exam, blood pressure, hemoglobin or hematocrit, pap smear, sexually transmitted disease (STD) testing and treatment, pregnancy testing, education, counseling and appropriate referral and follow-up. Preconception education and infertility counseling and referral are also to be provided, as well as information and education on DES, Rubella, STDs, smoking, drugs and alcohol, breast self-exam and abnormal pap smears. Education to community groups should include but not be limited to these topics: abstinence, birth control methods, sexual decision making, parent involvement, resisting sexual coercion, sexually transmitted diseases, puberty, and other topics related to family planning and sexual decisions and health.

The mission of the Reproductive Health Program which guides the use of the Title X Family Planning Services funds and allocated Title V funds is to provide comprehensive, quality and cost-effective reproductive health services to individuals in targeted areas. Individuals receiving services may reside outside of the target area.

This RFP is for the solicitation of multiple proposals to assure statewide Title X Family Planning Services. Entities submitting proposals are to describe the geographic area for which they propose to provide services. See Sections I and II, pages 6 and 9-10 for more details.

C. Federal and State Priorities for Services

The Federal Title X Family Planning priorities that must be incorporated into program planning and delivery are:

1. Assuring ongoing high quality family planning and related preventive health services that will improve the overall health of individuals;
2. Assuring access to a broad range of acceptable and effective family planning methods and related preventive health services that include natural family planning methods, infertility services, and services for adolescents; highly effective contraceptive methods; breast and cervical cancer screening and prevention that corresponds with nationally recognized standards of care; STD and HIV prevention, education, counseling, and testing; extramarital abstinence education and counseling; and other preventive health services. The broad range of services does not include abortion as a method of family planning;
3. Encouraging participation of families, parents, and/or other adults acting in the role of parents in the decision of minors to seek family planning services, including activities that promote positive family relationships;
4. Improving the health of individuals and communities by partnering with community-based organizations (CBOs), faith-based organizations (FBOs), and other public health providers that work with vulnerable or at-risk populations; and

5. Promoting individual and community health by emphasizing family planning and related preventive health services for hard-to-reach populations, such as uninsured or under-insured individuals, males, persons with limited English proficiency, adolescents, and other Legislative Mandates. (See Section IIA for mandates.)

As a condition of receiving Title V Maternal and Child Health Services funds, the Department conducts a comprehensive needs assessment every five years, and identifies priority maternal and child health needs. The most recent assessment was completed in 2005 and ten priorities were identified. Respondents to this RFP are encouraged to consider those priorities of relevance to reproductive health services and community education and which are shown in *Italics* in the following listing.

1. *Reduce the rates of overweight women, youth, and children by increasing participation in sufficient physical activity and improving nutrition.*
2. *Reduce the percent of women of child-bearing age, particularly pregnant and post-partum women, and adolescents who use tobacco and reduce the percent of infants, children and youth exposed to second hand smoke*
3. *Reduce rates of premature and low birth weight births for all women, with attention to adolescent pregnancy.*
4. Reduce the rates of hospitalizations and deaths due to unintentional injuries for children and youth.
5. *Reduce the number and rates of child abuse, neglect, and intentional injuries of children.*
6. *Reduce the rates of infant mortality, especially racial/ethnic disparities.*
7. Reduce alcohol use among youth.
8. *Increase capacity of community-based medical home providers to detect and refer for treatment women, children, and youth with emotional and behavioral health conditions.*
9. Increase capacity of Title V Programs for Children with Special Health Care Needs to serve increased numbers of children meeting medical and financial eligibility criteria and who are uninsured or underinsured.
10. Build capacity of Title V programs for Children with Special Health Care Needs to provide transition medical and dental clinics for youth with special health care needs 14-21 years of age.

D. Eligibility Requirements

Applicants must meet all of the following minimum qualifications to be eligible to respond to this RFP and to receive funds:

1. Be a Nebraska public or private non-profit organization or a federally recognized Native American Tribe headquartered in Nebraska.
2. For respondents claiming private non-profit status, provide with the proposal either a certification from the State of Nebraska, Office of Secretary of State or a letter from the Department of Treasury, Internal Revenue Service (IRS).

E. Developing the Proposal

The Department, the Office, and the Program believe that collaboration and community involvement are important in the planning and delivery of public health programs. Diverse representation, participation and leadership is crucial to assure that the views, perspectives and needs of community members are represented. Entities responding to this RFP should strive to collaborate with a broad cross-section of community representatives. In a collaboration centered on reproductive health services these representatives must include physicians, other public health agencies and programs, social services, community action agencies, pharmacists, substance abuse and domestic violence programs, minority health providers and advocates, hospital and health center representatives, and private citizens.

F. RFP Timeline

Issuance of RFP	August 8, 2006
Deadline for submission of written questions	October 2, 2006
Proposals due	October 9, 2006 by 5:00 pm CDT
Award notices/denials sent to respondents	November 15, 2006 (approximate)
Effective date of subgrant award	January 1, 2007

Details on submission of the proposal are found in SECTION III.

G. Questions and Requests for Information

From the date the RFP is issued until a determination is made and announced regarding the selection of subgrantee(s), contact between potential subgrantees and individuals employed by the Department regarding the RFP is restricted only to written communication with the staff designated as the point of contact in this RFP.

Responses to questions will be on the Office of Family Health web site at: www.hhs.state.ne.us/fah/fahindex.htm . The site will be updated every 72 hour period, Monday-Friday excluding holidays. Please check the site before submitting questions as the question may have already been asked and answered.

Submit questions and requests for information to Julie Reno in writing by one of the following methods (listed in order of preference) and clearly marked “**Title X Family Planning Services, Nebraska**”:

E-mail: julie.reno@hhss.ne.gov

Fax: (402) 471-1541

Mail: **Julie Reno**
Office of Family Health
Nebraska Department of Health and Human Services Regulation and Licensure
301 Centennial Mall South, P.O. Box 95007
Lincoln, NE 68509-5007

Faxed questions must include a cover sheet clearly indicating the number of pages transmitted. Faxes must also reference the RFP for the Title X Family Planning Services grant program on the cover sheet. The State assumes no liability for assuring accurate or complete fax transmission or receipt.

H. Proposal Review Process

1. Review for Compliance with Minimal Proposal Requirements and Scoring

Each proposal that complies with the Minimal Proposal Requirements outlined in Section III(B) will be evaluated and scored by a review committee on a scale of 0 to 100 points. Proposals will then be ranked and forwarded to the Director of the Department of Health and Human Services Regulation and Licensure for consideration and a decision on funding.

The criteria to be used for scoring and the maximum possible value of each section is as follows:

SECTION/CRITERIA	MAXIMUM POINTS
NARRATIVE AND WORK PLAN <ul style="list-style-type: none"> • Adequacy of needs assessment in identifying reproductive health needs of low income persons in target area • Degree to which proposal addresses these identified needs • Number of patients, particularly low income patients, to be served • Degree to which proposal addresses Title X and other federal and state requirements, including geographic access • Level of collaboration with community partners 	40
APPLICANT CAPACITY <ul style="list-style-type: none"> • Adequacy of facilities and staff for delivering proposed services • Capacity of entity to make rapid and effective use of federal funds • History of successfully providing services and administering programs, especially to low income individuals • Ability to bill and collect patient fees, including third party payments 	40
BUDGET AND BUDGET JUSTIFICATION <ul style="list-style-type: none"> • Reasonableness of costs in relationship to proposed services and costs 	20

are allowable	
<ul style="list-style-type: none"> Relative availability of non-federal resources and the degree to which resources are committed to the proposed services, including projected program income 	
TOTAL	100

2. Review of Applicant Capacity

As part of the scoring and selection process, the Department will assess an entity's capacity to provide reproductive health services to low income persons, provide education to community groups, and submit timely and accurate reports, invoices and fiscal documentation. The Department reserves the right to consider an entity's performance in current and/or prior grants, contracts, cooperative agreements, or subcontracts with the Department or other State of Nebraska agencies.

3. Geographic Access

The Department will consider geographic access in making final funding decisions. The Department reserves the right to fund more than one entity in a given geographic area if deemed necessary to assure adequate level of service to all target populations in that area. The Department also reserves the right to modify a proposed service area in circumstances where otherwise acceptable proposals have overlapping or redundant proposed service areas not necessary to serve target populations.

4. Notification of Decision

Each entity submitting a proposal, whether selected for funding or denied, will be notified in writing of the funding decision. Applicants may receive, upon written request directed to the Program the consensus review tool summary page for their proposal, which provides the score and overall strengths and weaknesses of their proposal.

5. Conditions

Award notices may be tentative, pending satisfactory resolution of conditions. A tentative award letter will be accompanied by a description of conditions, actions needed to remove those conditions, and the required time frame. Should the conditions not be met satisfactorily within the given time frame, the Department reserves the right to rescind the award. Expenses against the tentative award cannot be incurred after 30 days of receipt of the notice that the award is being rescinded.

SECTION II. SCOPE OF WORK

Proposals are being solicited for the provision of Title X Family Planning and related reproductive health services.

A. Required Services and other Mandates

Federally required Title X Family Planning Services are prescribed by Title X Population Research and Voluntary Family Planning Programs (statute), 45CFR59 Grants for Family Planning Services Subpart A (implementing regulations), and Program Guidelines For Project Grants For Family Planning Services United States Department of Health and Human Services Office of Public Health and Science Office of Population Affairs Office of Family Planning, January 2001 (federal guidance). These documents are found as Attachments 1, 2, and 3, respectively. Proposals must address capacity and plans to provide required services. In addition, proposals must address applicable State of Nebraska statutes and regulations that in turn govern the provision of these services.

Federally Required Services

The following listing describes the federally required clinical services. More detailed information is found in Attachment 3, Program Guidelines For Project Grants For Family Planning Services United States Department of Health and Human Services Office of Public Health and Science Office of Population Affairs Office of Family Planning, January 2001. Referenced sections are from that attachment.

1. Client Education – Delegates must have written plans for client education; See section 8.1, Attachment 3 for content and specific instructions on Method-Specific Informed Consent.
2. Counseling, including Method Counseling and Sexually Transmitted Disease (STD) and HIV Counseling; See section 8.2.
3. History, Physical Assessment, and Laboratory Testing; See section 8.3 for details, including required laboratory procedures.
4. Fertility Regulation – Delegates must comply with the guidance in section 8.4 regarding Reversible Contraception. Nebraska Title X Family Planning Funds are not used for permanent contraception (sterilization).
5. Infertility Services – Delegates must provide Level I services as described in section 8.5 and may optionally provide Level II as part of their Title X program.
6. Pregnancy Diagnosis and Counseling – See section 8.6 for details, including requirements for neutral, factual information and nondirective counseling for pregnant women on the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination.
7. Adolescent Services – Section 8.7 outlines requirements for counseling and education, confidentiality, family involvement, and resisting coercion.
8. Identification of Estrogen-Exposed Offspring – As part of the medical history, clients born between 1940 and 1970 should be asked if their mothers took estrogens during their pregnancies, with those exposed receiving appropriate follow-up as per section 8.8.

These federally required services must be delivered in accordance with federal and state requirements for licenses, certifications, and permits as applicable. These include, but are not limited to:

- Clinical Laboratory Information Act of 1988 (CLIA) – federal requirements for laboratory services
- 175NAC7 – State of Nebraska regulations for health clinics
- 175NAC8 – State of Nebraska regulations for pharmacies
- 175NAC134 – State of Nebraska regulations for Public Health Clinics Operating with a Drug Dispensing Permit

Furthermore, clinicians providing services shall perform those services within their scope of practice and have current State of Nebraska licenses as applicable. Each Delegate must have a qualified project director and a medical director, as described in section 6.5 of Attachment 3.

Other Federal Requirements

In addition to required clinical services, Title X Family Planning delegates must comply with federal requirements for Financial Management, Facilities and Accessibility of Services, Personnel, Training and Technical Assistance, Reporting Requirements, Review and Approval of Informational and Educational Materials, Community Participation, Education, and Project Promotion, Publications and Copyright, and Inventions or Discoveries, as described in sections 6.1 to 6.11 of Attachment 3. Furthermore, delegates must assure clinic management policies and procedures meet the requirements described in sections 10.1 to 10.4 of Attachment 3.

Included in the Financial Management requirements cited above are requirements specific to Charges, Billing and Collections. Because Title X Family Planning Services are targeted to low income persons, clients must not be denied project services or be subjected to any variation in quality of services because of the inability to pay. Title X Family Planning Services must be provided at no charge to individuals with incomes at or below 100% of the federal poverty guidelines. Charges for other patients must be based on a cost analysis of all services provided by the project. A schedule of discounts must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to services for those patients with incomes from 101% of the federal poverty guidelines up to 250%. The lowest segment of the scale would optimally be set at 20% of full fee but be no more than 33%. Further details on charges, billings and collections are found in section 6.3 of Attachment 3.

Included in the Review and Approval of Informational and Educational Materials section also cited above is the requirement for an advisory committee to review all informational and educational materials. Delegate(s) chosen through this RFP must establish an advisory committee of five to nine members in accordance with this requirement. See section 6.8 of Attachment 3 for full details.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 is applicable to health plans, hospitals, physicians and other health providers, including Title X Family Planning providers, known as “covered entities.” HIPAA regulations cover privacy, security and transaction codes.

Further guidance on interpreting statutory requirements that no Title X funds be used in programs for which abortion is a method of family planning are found in Attachment 4, Federal Register, Vol. 65, No. 128, July 3, 2000, Notices.

Nebraska Reproductive Health Program Requirements

Detailed guidance for the provision of family planning services are provided in two manuals: the Medical Policies and Procedures Manual and the Administrative Policies and Procedures Manual. Both are available upon written request. See Section I (G) page 4 of this RFP for instructions for requesting information. These manuals incorporate federal requirements cited above as well as state-specific requirements.

In addition to compliance with the above policies and procedures, the Program expects delegates to plan and deliver programs that meet the needs of low income persons in their communities. To do so, entities submitting proposals are to provide a summary of assessed needs and goals and objectives for addressing those needs. See Section IIIB later in this RFP for further details.

To assure high quality and cost effective STD testing, chlamydia screening is to be performed in accordance with Region VII Infertility Chlamydia Screening Guidelines, found as Attachment 5. Detailed guidance is available in the Screening and Treatment Guidelines, available upon request.

To maximize Title X Family Planning Services funds, delegates are to be enrolled Medicaid providers. Further, Title X Family Planning programs are eligible to purchase drugs at reduced price through the Public Health Service Section 340B Drug Pricing Program. Delegate(s) selected through this RFP will be enrolled in this program by the Department and provided detailed guidance on its use.

To assure geographic access statewide to the greatest numbers of potential users of family planning services, entities are strongly encouraged to provide services in population centers within their proposed geographic areas. Preference will be given to entities proposing that all clinical services are provided at any given site (health history, exam, and pharmacy), therefore reducing barriers to services.

Preference will be given to entities proposing services in identified medically underserved areas, culturally and ethnically diverse communities and with particular attention to serving low income clients.

Outside of Lincoln and Omaha preference will be given to potential delegates that propose the primary and/or satellite clinical sites in a location with the largest population base for that area therefore increasing potential level of service to the population. The Program considers the following cities/communities to be desirable sites for family planning clinic sites, either primary or satellite:

Gering or Scottsbluff
Chadron or Alliance
Valentine

O'Neill or Neligh
Broken Bow, Ord, Loup City or St. Paul
South Sioux City

North Platte	Norfolk
McCook	Columbus
Lexington	Fremont
Kearney	York or Seward
Grand Island	Beatrice
Hastings	Tecumseh, Syracuse or Falls City
Ogallala	

Entities may propose other sites, either in addition to or in place of these sites, but with clear rationale and justification. See Attachment 11 for definition of primary and satellite sites. See Section III for details of proposal content/format.

Terms and Assurances

Delegate(s) chosen through this RFP process are legally required to comply with the Subgrant Terms and Assurances, its Exhibits, and Certifications, found as Attachment 6. Any questions about the content should be addressed prior to signing and submitting the proposal.

B. General Expectations for Proposals

1. Projects must involve members of the target community in the planning and implementation of work plan activities.
2. Proposed budget must be reasonable for the proposed quantity and quality of activities in the work plan. A Budget Justification must be included following the proposed budget.
3. The Department reserves the right to withdraw any award if a satisfactory response to conditions has not been received by the Department within 30 calendar days of notice to the Subgrantee by the Department.
4. The Department will not reimburse expenses associated with preparing and submitting a proposal.
5. The Department reserves the right to withdraw any award or negotiate the Scope of Work of any proposed project or proposed project components.
6. The entity submitting a proposal certifies that it has appropriate systems and controls in place to ensure that federal funds will not be used in the performance of this grant for the acquisition, operation or maintenance of computer software in violation of copyright laws.
7. Upon receipt of an acceptable response to conditions, the Department will send to each Delegate a final award letter. This award will incorporate by reference the RFP, the Delegate's proposal, and the Delegate's response to the conditions.

C. Additional Post-award Expectations

1. Delegates are to expend funds in accordance with the approved line item budget. If changes in line items exceed 10% of the award or if staffing patterns need to be changed, the Delegates must request a budget revision or a grant amendment depending on what in the budget needs to be changed. It is up to the discretion of the Department whether or not to approve the requested budget revision or award amendment.
2. Six equal payments of Title X and Title V funds will be made to the delegate every other month in anticipation of expenses to be incurred in the upcoming two month period. These payments will be one sixth of the annual awarded amounts for each federal source. In turn, the Delegate is to submit a report of expenditures by revenue source, including both federal sources, program income, and in-kind, by the 20th of the month following the two month period for which payment was made. The reports of expenditures will be reviewed to determine if allowable, allocable, and reasonable, and that procedures were maintained to minimize the time elapsing between the payment of funds and their disbursement by the delegate in accordance with 45CFR92. Any unallowable costs identified will result in adjustments in future payments. All payments are subject to the availability of federal funds.
3. Delegates are to be knowledgeable of and utilize standard payroll practices including State and Federal tax withholding requirements.
4. Delegates are to maintain accounting records of actual expenditures. The records include but are not limited to: Accounting books, ledgers, documents, payroll records, including signed timesheets, etc., following standard accounting procedures and practices that properly reflect all direct and indirect expenses related to this grant award. These records shall be kept and made available for three (3) years from the date of the final payment.
5. Delegates' financial statements are subject to an audit performed by a licensed certified public accountant. The audited financial statements and federally-required reports, if needed, must be submitted to the Department within nine (9) months following the close of the Delegate's fiscal year. The audit expense is proportionately reimbursable from the grant funds. Therefore, the cost should be included in the proposed budget.
6. Delegates are to maintain accurate records regarding the program and submit required reports. Specific reporting requirements are outlined in Exhibit 1 of Attachment 6.
7. Delegates are to be aware that the Department may withhold payment of invoices for lack of documented and/or timely progress, as well as any apparent non-compliance with grant requirements.
8. If not included with its proposal, within 30 days of notice of award, delegate(s) selected through this RFP are to submit to the Department the following:
 - Referral list (those agencies and providers to which Title X Family Planning patients in the target area will be referred for needed services not provided by delegate)
 - Fee schedule

9. If not included with its proposal, within 60 days of notice of award, delegate(s) selected through this RFP are to submit administrative and clinical policies and procedures, including those for billing and collections and those for cost analysis and fee determination.

D. Use of Funds

Title X Family Planning Services funds are to be used for allowable, reasonable and allocable costs to provide Title X Family Planning services. Title V Maternal and Child Health Services funds are to be expended to support community education activities. OMB Circulars A-21, A-87, and A-122 provide guidance on cost principles for federal funds and may be found at www.whitehouse.gov/OMB/circulars/index.html. Attachment 4 provides clarification on the requirement that no funds appropriated under Title X be used in programs in which abortion is a method of family planning.

Grant related program income is required and must be used to further the program and cannot be used for another program. All program income must be carried forward and accounted for on the next year's budget and expenditure reports. Federal grant funds and grant related program income cannot be used for costs associated with fund raising events. Grant related program income is income from any non-Federal source, including, but not limited to: income from fees for services performed (patient fees and third party reimbursements; Medicaid and Medicare reimbursements are considered program income, not direct federal resources), voluntary donations, the use or rental of real or personal property acquired under federally-funded projects, the sale of commodities or items fabricated under an award, and license fees and royalties on patents and copyrights.

Funding will be granted using the described funding formula, Attachment 11 for an identified time period. If a primary or satellite site is closed by the grantee or deemed not viable by the grantor during that identified time period, funds will be returned to the grantor on a prorated basis for the time period that the site is no longer in operation.

SECTION III. PROPOSAL REQUIREMENTS

A. General Instructions

Read all instructions carefully. Proposals must address all the proposal and submission requirements set forth in this RFP. Proposals will be evaluated on overall quality of content and responsiveness to the purpose and specifications of this RFP. Only those proposals that include complete information as required by this RFP will be considered for evaluation. Throughout the following instructions, "you" and "your" refer to the entity submitting a proposal.

NOTE: In submitting a proposal, an entity agrees that the Department is authorized to verify any claimed information. All proposals received by the Department are subject to the provisions of the public records act and are not considered confidential after completion of the selection process.

B. Minimum Proposal Requirements

All proposals must include the items listed in this Section. Assemble all materials in the order listed below. Page limits and samples are noted, when relevant. Unless otherwise specified, no particular form is required.

1. Proposal Cover Sheet

Complete all sections of the Proposal Cover Sheet (Attachment 7), and provide the signature of your organization's legally authorized official. The Cover sheet should be the top page of the proposal.

2. Table of Contents

Include a Table of Contents that provides page numbers for the headings that follow in this Section (III (B) 3 through 8).

3. Project Narrative (20 page maximum)

The Narrative is to be a twenty-page (or less) overview of the proposed project. The purpose of the Narrative is to give reviewers a general understanding of needs to be addressed and the services being proposed. The narrative shall address:

- a) Needs Assessment – Indicate which county or counties for which services are being proposed, and summarize your assessment of the needs of low income persons in these county(ies) for reproductive health services. This assessment should be based on data collected by your organization, on assessments made by your community or community collaborators, published state and national data, and other sources. This needs assessment is to be inclusive of at-risk populations, including but not limited to low income persons, racial/ethnic minorities, persons with limited English proficiency, persons with disabilities, homeless and incarcerated persons, adolescents, and victims of domestic violence. The needs assessment must conclude with your determination of the highest priority needs for reproductive health services in your targeted area.
- b) Proposed Services – Provide an overview of your proposal to meet the priority needs identified through the needs assessment. This description should include geographic area to be served, locations where services will be provided, and how they will be organized. Include details on hours of operation, the services to be provided at each location, and methods for assuring federal and state requirements will be met. Include rationale for selection of primary and satellite site(s). Indicate the projected number of persons to be served by site, broken down by numbers at or below 100% of the federal poverty level and numbers of persons from 101% to 150% and 151% up to 250% of the federal poverty level. Community collaborators should be identified, as well as any proposed contractors.

4. Work Plan

Use the work plan form found as Attachment 8 to display your proposed goal(s), objectives and activities for family planning and related reproductive health services. For entities not

currently Title X delegates or delegates that are not currently providing services in the targeted areas, the work plan should reflect what you determine to be key start up activities and realistic time frames for full operation. Goals and objectives should be reflective of your community needs assessment, program requirements, and identified priorities. Action steps should provide enough detail to assure reviewers that you have a clear understanding of and plan for delivering high quality family planning and related reproductive health services.

5. Capacity to Provide Services

Complete Attachment 9, describing your capacity to carry out the proposed project. For those activities to be carried out by a contractor, complete a separate form for that contractor. Be reminded, though, that only the Delegate(s) selected through this competition is to carry out financial management and project oversight activities.

6. Project Budget and Budget Justification

Use the Budget Worksheet (Attachment 10) to display the budget for the proposed project. Show detail by revenue source Title X, Title V, Program Income, and In-kind. All revenue sources will be considered in evaluating and approving the budget.

Attach a separate budget justification that is provided in sufficient detail to support one-step below the object class category level for both federal grant funds and grant related program income. The budget categories are to reflect proposed costs for the following categories:

Salaries: For each staff position budgeted in the Budget Worksheet, include the title of the position, the FTE, annual salary, number of months salary requested, and a brief summary of the job description or responsibilities. For occupied positions, include name of staff person. If vacant, indicate as such.

Benefits: Describe computation used for estimating cost of benefits and itemize the components included in benefits (e.g., health insurance, FICA, life insurance, retirement plan, etc.).

Contracted Services: Descriptions of proposed contracts for project activities need to be included along with anticipated cost for each contract. Include descriptions of the following for each proposed contract: (a) Scope of Work, including tasks and deliverables; (b) time period of the contract; (c) person in your agency who will supervise or manage the contract, and (d) name of the contractor or if not yet known, what method will be used to select the contractor, e.g. solicitation of bids, sole source, etc.

Supplies: This category includes clinic supplies, contraceptives, office supplies, educational supplies, meeting supplies, and other materials necessary for carrying out the work proposed. Identify and explain by type of supply.

Travel: Include estimates of all travel relative to the Scope of Work proposed, including travel related to staff development. Describe in sufficient detail to understand purpose of travel and how cost was estimated.

Other: Describe costs for this category that includes items such as telephone, copying, printing, postage, mailing, publicity, publications, insurance, audits and accounting services, legal fees, marketing, and computer time directly related to this grant's activities.

Indirect Costs: Entities with a current indirect cost agreement with a federal or state agency may include indirect costs as a line item. A copy of the current agreement must be included in the budget documents. Indirect costs are those that have been incurred for common or joint purposes. These costs benefit more than one cost objective and cannot be readily identified with a particular final cost objective without effort disproportionate to the result achieved.

Because of the diverse characteristics and accounting practices of public and private non-profit entities, the types of cost which may be classified as indirect costs, cannot be specified in all situations. However, typical examples of indirect costs may include certain general administrative activities of the agency, accounting and personnel services performed within the agency, and the costs of operating and maintaining facilities.

In contrast, direct costs include:

- 1) Compensation of employees for the time devoted and identified specifically to the performance of this award.
- 2) Cost of materials acquired, consumed, or expended specifically for the purpose of the award.
- 3) Equipment specifically for the purpose of the award
- 4) Travel expenses incurred to carry out this grant.

7. Assurance Forms

The Proposal Cover Sheet (Attachment 7) and the Certification Forms found within the Terms and Assurances (Attachment 6) must be signed and dated by an official authorized to bind your agency. By signing the pages, the official verifies that the following statement is true: potential Delegate and its potential contractor(s) will abide by the Departments Subgrant Terms and Assurances.

Please note that signatures are required in five places within Attachment 6. Insert the Terms and Assurances with the signed Certification forms immediately after the Subgrantee Capacity form.

8. Letters of Support

Applicants may attach letters of support from community partners or collaborators if deemed appropriate.

C. Preparation and Submission Instructions

- Use 8 1/2" x 11" white paper only, typed. Number each page of the proposal consecutively. The type font size is to be no less than 12 characters per inch, in an easy to read font such as New Times Roman. Page limits assume lines that are single-spaced.
- Submissions in response to the RFP must contain the proposal and all required supporting information in one package, securely clipped, not stapled, in the upper left corner. Folders and binders are not necessary or desired.
- One original and four (4) copies of the proposal must be submitted.
- The Proposal Cover Sheet must be the top page of the proposal.
- Submission by fax, e-mail, or disk will not be accepted because original signatures are required on the Cover Sheet and Certifications.
- Mail or deliver a complete, signed original and four copies **on or before Monday, October 9, 2006**. If mailed, proof of mailing on or before the closing date will be strictly observed. Additions or corrections will not be accepted after the closing date. Applicants are strongly encouraged to use registered mail or at least first-class mail. Do not send third class or book rate.
- Proof of mailing consists of one of the following three options through either the U.S. Postal Service or a commercial carrier:
 1. U.S. Postal Service
 - A legibly dated U.S. Postal Service postmark printed or stamped on the envelope (NOTE: the U.S. Postal Services does not uniformly provide a dated postmark. Check with the local post office in advance before relying on this method of delivery).
 - A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
 2. Commercial Carrier
 - A dated shipping label, invoice, or receipt from a commercial carrier, e.g. Federal Express.
- The following methods are not valid proof of mailing:
 - A private metered postmark
 - A mail receipt that is not dated by the U.S. Postal Service.
- Keep a copy of the proof of mailing for your documentation.
- Proposals hand delivered or by courier services will be received during business hours (8:00 a.m. to 5:00 p.m. CDT, Monday – Friday, excluding state-observed holidays). Hand delivery or courier services will be received at the 3rd floor reception desk, NHHS, 301 Centennial Mall South, Nebraska State Office Building, Lincoln, Nebraska. Proposals hand delivered or

by courier must be received at the NSOB no later than **5:00 p.m., Monday, October 9, 2006.**

- Omission of any required document or form, failure to use required formats or response, or failure to respond to any requirements may lead to rejecting the application prior to the review. **LATE PROPOSALS WILL BE REJECTED.**

Proposals are to be addressed to:

**Julie Reno, Interim Program Manager
Attn: Title X Family Planning Services, Nebraska
Office of Family Health
Nebraska Department of Health and Human Services Regulation and Licensure
301 Centennial Mall South, P.O. Box 95007
Lincoln, NE 68509-5007**

ATTACHMENTS

1. Title X – Population Research and Voluntary Family Planning Program
2. 42CFR59, Grants for Family Planning Services
3. Program Guidelines for Project Grants for Family Planning Services, US Department of Health and Human Services, Office of Public Health and Science, Office of Population Affairs, Office of Family Planning, January 2001
4. Fed. Register / Vol. 65, No. 128 / Monday , July 3, 2000 / Notices: DEPARTMENT OF HEALTH AND HUMAN SERVICES, Office of Public Health and Science, Provision of Abortion-Related Services in Family Planning Services Projects
5. Region VII Infertility Prevention Project Protocols
6. Subgrant Terms and Assurances
7. Cover Sheet
8. Work Plan form
9. Capacity to Provide Title X Family Planning Services form
10. Budget Worksheet
11. Title X Family Planning Funding Formula

Attachment 1

TITLE X
POPULATION RESEARCH AND
VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES
SEC. 1001 [300]

(a)The Secretary is authorized to make grants to and enter into contracts with

public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including

natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family [1] participation in projects assisted under this subsection.

(b)In making grants and contracts under this section the Secretary shall take

into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c)The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment

on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

d)For the purpose of making grants and contracts under this section, there are authorized to be appropriated \$30,000,000 for the fiscal year ending June 30, 1971; \$60,000,000 for the fiscal year ending June 30, 1972; \$111,500,000 for the fiscal year ending June 30, 1973, \$111,500,000 each for the fiscal years

ending June 30, 1974, and June 30, 1975; \$115,000,000 for fiscal year 1976;

\$115,000,000 for the fiscal year ending September 30, 1977;

\$136,400,000 for the fiscal year ending September 30, 1978;

\$200,000,000 for the fiscal year ending September 30, 1979;

\$230,000,000 for the fiscal year ending September 30, 1980;

\$264,500,000 for the fiscal year ending September 30, 1981;

\$126,510,000 for the fiscal year ending September 30, 1982;

\$139,200,000 for the fiscal year ending September 30, 1983;

\$150,030,000 for the fiscal year ending September 30, 1984; and

\$158,400,000 for the fiscal year ending September 30, 1985.

[1] So in law. See section 931(b)(I) of Public Law 97-35 (95 Stat. 570).
Probably should be
"family".

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES
SEC. 1002 [300a]

(a)The Secretary is authorized to make grants, from allotments made under

subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b) The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c) For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d) For the purpose of making grants under this section, there are authorized to be appropriated \$10,000,000 for the fiscal year ending June 30, 1971; \$15,000,000 for the fiscal year ending June 30, 1972; and \$20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS SEC. 1003 [300a-1]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$2,000,000 for the fiscal year ending June 30, 1971; \$3,000,000 for the fiscal year ending June 30, 1972; \$4,000,000 for the fiscal year ending June 30, 1973; \$3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; \$4,000,000 for fiscal year ending 1976; \$5,000,000 for the fiscal year ending September 30, 1977; \$3,000,000 for the fiscal year ending September 30, 1978; \$3,100,000 for the fiscal year ending September 30, 1979; \$3,600,000 for the fiscal year ending September 30, 1980; \$4,100,000 for the fiscal year ending September 30, 1981; \$2,920,000 for the fiscal year ending September 30, 1982; \$3,200,000 for the fiscal year ending September 30, 1983; \$3,500,000 for the fiscal year ending September 30, 1984; and \$3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH SEC. 1004 [300a-2] The Secretary may -

- (1) conduct, and
- (2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS SEC. 1005 [300a-3]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$750,000 for the fiscal year ending June 30, 1971; \$1,000,000 for the fiscal year ending June 30, 1972; \$1,250,000 for the fiscal year ending June 30, 1973; \$909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; \$2,000,000 for fiscal year 1976; \$2,500,000 for the fiscal year ending September 30, 1977; \$600,000 for the fiscal year ending September 30, 1978; \$700,000 for the fiscal year ending September 30, 1979; \$805,000 for the fiscal year ending September 30, 1980; \$926,000 for the fiscal year ending September 30, 1981; \$570,000 for the fiscal year ending September 30, 1982; \$600,000 for the fiscal year ending September 30, 1983; \$670,000 for the fiscal year ending September 30, 1984; and \$700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

SEC. 1006 [300a-4]

(a) Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b) Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c) A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that--

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term ''low-income family'' shall be defined

by the Secretary in accordance with such criteria as he may prescribe so as to

insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008 [1] [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

[1] Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).

Title X Family Planning Program Regulations

[Code of Federal Regulations]
 [Title 42, Volume 1, Parts 1 to 399]
 [Revised as of October 1, 2000]
 From the U.S. Government Printing Office via GPO Access
 [CITE: 42CFR59]

[Page 407-416]

TITLE 42--PUBLIC HEALTH

CHAPTER I--PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 59--GRANTS FOR FAMILY PLANNING SERVICES

Subpart A--Project Grants for Family Planning Services

- Sec.
- 59.1 To what programs do these regulations apply?
 - 59.2 Definitions.
 - 59.3 Who is eligible to apply for a family planning services grant?
 - 59.4 How does one apply for a family planning services grant?
 - 59.5 What requirements must be met by a family planning project?
 - 59.6 What procedures apply to assure the suitability of informational and educational material?
 - 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?
 - 59.8 How is a grant awarded?
 - 59.9 For what purposes may grant funds be used?
 - 59.10 What other HHS regulations apply to grants under this subpart?
 - 59.11 Confidentiality.
 - 59.12 Additional conditions.

Subpart B [Reserved]

Subpart C--Grants for Family Planning Service Training

- 59.201 Applicability.
- 59.202 Definitions.
- 59.203 Eligibility.
- 59.204 Application for a grant.
- 59.205 Project requirements.
- 59.206 Evaluation and grant award.
- 59.207 Payments.
- 59.208 Use of project funds.
- 59.209 Civil rights.
- 59.210 Inventions or discoveries.
- 59.211 Publications and copyright.
- 59.212 Grantee accountability.
- 59.213 [Reserved]
- 59.214 Additional conditions.
- 59.215 Applicability of 45 CFR part 74.

Subpart A--Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a-4.

[[Page 408]]

Source: 65 FR 41278, July 3, 2000, unless otherwise noted.

Sec. 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Sec. 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). ``Low-income family'' also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, et al.), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Sec. 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

Sec. 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume

on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain--

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

Sec. 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and

[[Page 409]]

may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.\1\

\1\ Section 205 of Pub. L. 94-63 states: ``Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.''

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by Sec. 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral

[[Page 410]]

to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to--

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Sec. 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) Size. The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) Composition. The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) Function. In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

[[Page 411]]

(v) Establish a written record of its determinations.

Sec. 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

- (1) The number of patients, and, in particular, the number of low-income patients to be served;
- (2) The extent to which family planning services are needed locally;
- (3) The relative need of the applicant;
- (4) The capacity of the applicant to make rapid and effective use of the federal assistance;
- (5) The adequacy of the applicant's facilities and staff;
- (6) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and
- (7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

Sec. 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompet for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

Sec. 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the

approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

Sec. 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

37 CFR Part 401--Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
 42 CFR Part 50, Subpart D--Public Health Service grant appeals procedure
 45 CFR Part 16--Procedures of the Departmental Grant Appeals Board
 45 CFR Part 74--Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments
 45 CFR Part 80--Nondiscrimination under programs receiving Federal assistance through the Department of Health and

[[Page 412]]

Human Services effectuation of Title VI of the Civil Rights Act of 1964
 45 CFR Part 81--Practice and procedure for hearings under Part 80 of this Title
 45 CFR Part 84--Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
 45 CFR Part 91--Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
 45 CFR Part 92--Uniform administrative requirements for grants and cooperative agreements to state and local governments

Sec. 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

Sec. 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Subpart B [Reserved]

Subpart C--Grants for Family Planning Service Training

Authority: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-1.

Source: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

Sec. 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a-1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

Sec. 59.202 Definitions.

As used in this subpart:

- (a) Act means the Public Health Service Act.
- (b) State means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.
- (c) Nonprofit private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.
- (d) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.
- (e) Training means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

Sec. 59.203 Eligibility.

- (a) Eligible applicants. Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.
- (b) Eligible projects. Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: Provided, That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

[[Page 413]]

Sec. 59.204 Application for a grant.

- (a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe. \1\ The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements

of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

\1\ Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a-1, and 300a-4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

Sec. 59.205 Project requirements.

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

Sec. 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the

delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to

[[Page 414]]

program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in Sec. 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

Sec. 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

Sec. 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

(1) Return travel to the trainee's point of origin.

(2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

Sec. 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the

[[Page 415]]

approval of the President (45 CFR part 80).

Sec. 59.210 Inventions or discoveries.

Any grant award pursuant to Sec. 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

Sec. 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any

publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

Sec. 59.212 Grantee accountability.

(a) Accounting for grant award payments. All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: Provided, however, That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) Accounting for grant-related income--(1) Interest. Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) Grant closeout--(1) Date of final accounting. A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) Final settlement. There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or

[[Page 416]]

assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

Sec. 59.213 [Reserved]

Sec. 59.214 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

Sec. 59.215 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR Part 74

Subpart:

- A General.
- B Cash Depositories.
- C Bonding and Insurance.
- D Retention and Custodial Requirements for Records.
- F Grant-Related Income.
- G Matching and Cost Sharing.
- K Grant Payment Requirements.
- L Budget Revision Procedures.
- M Grant Closeout, Suspension, and Termination.
- O Property.
- Q Cost Principles.

[38 FR 26199, Sept. 19, 1973]

Program Guidelines
For Project Grants
For Family Planning Services

United States Department of Health and Human Services
Office of Public Health and Science
Office of Population Affairs
Office of Family Planning
4350 East West Highway, Suite 200
Bethesda, Maryland 20814

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Table of Contents

PART I1
1.0 Introduction to the Program Guidelines1
1.1 Definitions.1
2.0 The Law, Regulations, and Guidelines2
3.0 The Application Process.2
3.1 Eligibility2
3.2 Needs Assessment3
3.3 The Application3
3.4 Project Requirements4
3.5 Notice of Grant Award	5
4.0 Grant Administration.5
5.0 Legal Issues5
5.1 Voluntary Participation5
5.2 Confidentiality5
5.3 Conflict of Interest.6
5.4 Liability Coverage.6
5.5 Human Subjects Clearance (Research)6
6.0 Project Management6
6.1 Structure of the Grantee.6
6.2 Planning and Evaluation	7
6.3 Financial Management.7
6.4 Facilities and Accessibility of Services.9
6.5 Personnel9
6.6 Training and Technical Assistance	10
6.7 Reporting Requirements	10
6.8 Review and Approval of Informational Educational Materials.....	10
6.9 Community Participation, Education, and Project Promotion.....	11
6.10 Publications and Copyright.	12

6.11	Inventories or Discoveries	12
PART II.	13
7.0	Client Services.	13
7.1	Service Plans and Protocols	13
7.2	Procedural Outline.	13
7.3	Emergencies	15
7.4	Referrals and Follow-Up	16
8.0	Required Services.	16
8.1	Client Education	17
8.2	Counseling.	18
8.3	History, Physical Assessment, And Laboratory Testing.....	19
8.4	Fertility Regulation.	23
8.5	Infertility Services.	24
8.6	Pregnancy Diagnosis and Counseling.	24
8.7	Adolescent Services	25
8.8	Identification of Estrogen-Exposed Offspring .	26
9.0	Related Services.	26
9.1	Gynecologist Services	26
9.2	Sexuality Transmitted Diseases (STD) and HIV/AIDS.....	26
9.3	Special Counseling	27
9.4	Genetic Information and Referral	27
9.5	Health Promotion/Disease Prevention	27
9.6	Postpartum Care	27
10.0	Clinic Management.	27
10.1	Equipment and Supplies	27
10.2	Pharmaceuticals.	28
10.3	Medical Records.	28
10.4	Quality Assurance and Audit.	30

Attachments

- A. The Law: Title X Population Research and Voluntary Family Planning Programs
- B. Regulations: Grants for Family Planning Services under Title X of the Public Health Service Act
- C. Sterilization of Persons in Federally Assisted Family Planning Projects
- D. DHHS Regional Offices- Regional Program Consultants For Family Planning

Resource Documents

PART I

1.0 Introduction to the Program Guidelines

This document, Program Guidelines for Project Grants for Family Planning Services(Guidelines), has been developed by the Office of Population Affairs (OPA), U.S. Department of Health and Human Services (DHHS), to assist current and prospective grantees in understanding and utilizing the family planning services grants program authorized by Title X of the Public Health Service Act, 42 U.S.C. 300, et seq. The Office of Population Affairs also provides more detailed guidance, updated clinical information and clarification of specific program issues in the form of periodic Program Instructions to the Regional Offices.

This document is organized into two parts. Part I (sections 1-6) covers project management and administration, including the grant application and award process. Part II (sections 7-11) covers client services and clinic management.

Reference is made throughout the document to specific sections of the Title X law and implementing regulations, which are contained in Attachments A and B, respectively. (Reference to specific sections of the regulations will appear in brackets, e.g., [45 CFR Part 74, Subpart C].) Federal sterilization regulations are contained in Attachment C. The DHHS regional offices are listed in Attachment D. Selected other materials that provide additional guidance in specific areas are classified as Resource Documents.

1.1 DEFINITIONS

Throughout this document, the word "must" indicates mandatory program policy. "Should" indicates recommended program policy relating to components of family planning and project management that the project is urged to utilize in order to fulfill the intent of Title X. The words "can" and "may" indicate suggestions for consideration by individual projects.

The "grantee" is the entity that receives a Federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The "project" consists of those activities described in the grant application and supported under the approved budget. Delegate/contract agencies" are those entities that provide family planning services with Title X funds under a negotiated, written agreement with a grantee. "Service sites" are those locations where services actually are provided by the grantee or delegate/contract agency.

2.0 The Law, Regulations, and Guidelines

To enable persons who want to obtain family planning care to have access to such services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs" to the Public Health Service Act. Section 1001 of the Act (as amended) authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)" (see Attachment A). The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X [42 CFR Part 59, Subpart A] set out the requirements of the Secretary, Department of Health and Human Services, for the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act. Prospective applicants and grantees should refer to the regulations (see Attachment B). This document, Program Guidelines for Project Grants for Family Planning Services, interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

3.0 The Application Process

3.1 ELIGIBILITY

Any public or nonprofit private entity located in a state (which, by definition, includes the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands [Midway, Wake, et al.], the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services project grant [59.2, 59.3].

To promote the purposes of Section 1001 of the Act in the most cost effective and efficient manner, grants will be made to public and non-profit private entities to foster projects most responsive to local needs. A non-profit private agency, institution, or organization must furnish evidence of its non-profit status in accordance with instructions accompanying the project grant application form. Under the law, grants cannot be made to entities that propose to offer only a single method or an unduly limited number of family planning methods. A facility or entity offering a single method can receive assistance under Title X by participating as a delegate/contract agency in an approvable project that offers a broad range of acceptable and effective medically approved family planning methods and services [59.5(a)(1)].

3.2 NEEDS ASSESSMENT

An assessment of the need for family planning services must be conducted prior to applying for a competitive grant award. The needs assessment documents the need for family planning services for persons in the service area and should include:

- ~ Description of the geographic area including a discussion of potential geographic, topographic, and other related barriers to service;
- ~ Demographic description of the service area including objective data pertaining to individuals in need of family planning services, maternal and infant morbidity/mortality rates, birth rates and rates of unintended pregnancies by age groups, poverty status of the populations to be served, cultural and linguistic barriers to services, etc.;
- ~ Description of existing services and need for additional family planning services to meet community/cultural needs;
- ~ Need indicators that include rates of STDs and HIV prevalence (including perinatal infection rates) in the grantee area;
- ~ Identification and descriptions of linkages with other resources related to reproductive health; and
- ~ Identification and discussion of high priority populations and target areas.

Grantees should perform periodic reassessment of service needs. Competitive grant applications must include a full and updated needs assessment.

3.3 THE APPLICATION

The Department of Health and Human Services' Office of Population Affairs administers the Title X Family Planning Program through the DHHS Regional Offices. An annual announcement of the availability of Title X service grant funds sets forth specific application requirements and evaluation criteria. Applications must be submitted to the Office of Grants Management for Family Planning Services on the form required by the Department. The application forms are available from the Office of Grants Management for Family Planning Services. Assistance regarding programmatic aspects of proposal preparation is available from the Regional Office. For assistance with administrative and budgeting aspects of proposal preparation, contact the Office of Grants Management for Family Planning Services.

Unless otherwise instructed, applicants are to respond to the standard instructions contained in the application kit and to the PHS supplemental instructions. An application must contain:

- ~ a needs assessment
- ~ a narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the requirements of the law and regulations;

- ~ a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested [59.4(c)(2)] and which is consistent with the terms of Section 1006 of the Act, as implemented by regulation [59.7(b)];
- ~ a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project;
- ~ project objectives that are specific, realistic, and measurable; and
- ~ other pertinent information as required [59.4(c)(4)].

The application must address all points contained in section 59.7(a) of the regulations, which are the criteria DHHS Regional Offices will use to decide which family planning projects to fund and in what amount. The application shall not include activities that cannot be funded under Title X, such as abortion, fundraising, or lobbying activities.

3.4 PROJECT REQUIREMENTS

Projects must adhere to:

- ~ Section 59.5 and all other applicable provisions of the regulations, which list the requirements to be met by each project supported by Title X.
- ~ The applicable requirements of these Program Guidelines for Project Grants for Family Planning Services.
- ~ Other Federal regulations which apply to grants made under Title X [59.10]. For assistance in identifying other relevant regulations, contact the Regional Office.

3.5 NOTICE OF GRANT AWARD

The notice of grant award will inform the grantee how long DHHS intends to support the project without requiring it to re compete for funds [59.8]. This period of funding is called the "project period." The project will be funded in increments called "budget periods." The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All grantees must comply with the applicable legislative, regulatory and administrative requirements described in the Public Health Service Grants Policy Statement. A copy of the Public Health Service Grants Policy Statement may be obtained from the Office of Grants Management for Family Planning Services.

5.0 Legal Issues

5.1 VOLUNTARY PARTICIPATION

Use by any individual of project services must be solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use or not to use any particular method of

family planning. Acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other service or assistance from or participation in any other programs of the applicant [59.5(a)(2)].

Project personnel must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

5.2 CONFIDENTIALITY

Every project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11].

5.3 CONFLICT OF INTEREST

Grantees must establish policies to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others.

5.4 LIABILITY COVERAGE

Grantees and/or delegates/contractors should ensure the existence of adequate liability coverage for all segments of the project funded under the grant, including all individuals providing services. Governing boards should obtain liability coverage for their members.

5.5 HUMAN SUBJECTS CLEARANCE (RESEARCH)

Grantees considering clinical or sociological research using Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. A copy of these regulations may be obtained from the Regional Office. Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources in any segment of the project.

6.0 Project Management

6.1 STRUCTURE OF THE GRANTEE

Family planning services under Title X grant authority may be offered by grantees directly and/or by delegate/contract agencies operating under the umbrella of the grantee. However, the grantee is responsible for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by delegate/contract agencies. Grantees must therefore have a negotiated, written agreement with each delegate/contract agency and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Program Guidelines for Project Grants for Family Planning

Services, as well as other applicable requirements such as Subpart C of 45 CFR Part 74, or Subpart C of 45 CFR Part 92. If a delegate/contract agency wishes to subcontract any of its responsibilities or services, a written negotiated agreement that is consistent with Title X requirements and approved by the grantee must be maintained by the delegate/contractor. Delegate/contract agencies should be invited to participate in the establishment of grantee standards and guidelines.

6.2 PLANNING AND EVALUATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered. To meet these requirements, each competitive application must include a plan which identifies overall goals and specific measurable objectives for the project period. The objectives may be directed to all clients or to specific groups of clients and must be consistent with Title X objectives. The plan must include an evaluation component that addresses and defines indicators by which the project intends to evaluate itself.

6.3 FINANCIAL MANAGEMENT

Grantees must maintain a financial management system that meets the standards specified in Subpart C of 45 CFR Part 74 or Subpart C of 45 CFR Part 92, as applicable, as well as any other requirements imposed by the Notice of Grant Award, and which complies with Federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained as required.

~ Charges, Billing, and Collections

A grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project. The policies and procedures should be approved by the governing authority or board of the grantee and the Regional Office.

Clients must not be denied project services or be subjected to any variation in quality of services because of the inability to pay. Billing and collection procedures must have the following characteristics:

- (1) Charges must be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services must be given bills directly. In cases where a third party is responsible, bills must be submitted to that party.
- (2) A schedule of discounts must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees must be waived for individuals with family incomes above this amount who,

as determined by the service site project director, are unable, for good cause, to pay for family planning services.

- (3) Clients whose documented income is at or below 100% of the Federal poverty level must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services.
- (4) Individual eligibility for a discount must be documented in the client's financial record.
- (5) Bills to third parties must show total charges without applying any discount.
- (6) Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or delegate/contract agency level is required.
- (7) Bills to clients must show total charges less any allowable discounts.
- (8) Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.
- (9) Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.
- (10) A method for the "aging" of outstanding accounts must be established.
- (11) Voluntary donations from clients are permissible. However, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements set out above.
- (12) Client income should be re-evaluated at least annually.

Effective financial management will assure the short and long term viability of the project, including the efficient use of grant funds. Technical assistance in achieving this objective is available from the Regional Office. Title X projects offering services that are not required by the statute, regulations or these Guidelines should whenever possible seek other sources of funding for such services before applying Title X funds to those activities.

~ Financial Audit

Audits of grantees and delegate/contract agencies must be conducted in accordance with the provisions of 45 CFR Part 74, Subpart C, and 45 CFR Part 92, Subpart C, as applicable. The audits must be conducted by auditors meeting established criteria for qualifications and independence.

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet applicable standards established by the Federal, state and local governments (e.g., local fire, building and licensing codes).

Projects must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap in Federally assisted programs and activities, and which requires, among other things, that recipients of Federal funds operate their Federally assisted programs so that, when viewed in their entirety, they are readily accessible to people with disabilities. A copy of Part 84 may be obtained from the Regional office. Projects must also comply with any applicable provisions of the Americans With Disabilities Act (Public Law 101-336).

Emergency situations may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.

6.5 PERSONNEL

Grantees and delegate/contract agencies are reminded of their obligation to establish and maintain personnel policies that comply with applicable Federal and state requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title I of the Americans With Disabilities Act. These policies should include, but need not be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures. Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to and able to deal effectively with the cultural and other characteristics of the client population [59.5 (b)(10)].

Grantees must also ensure that:

- ~ Projects are administered by a qualified project director;
- ~ The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning;
- ~ Protocols exist that provide all project personnel with guidelines for client care;
- ~ Personnel records are kept confidential;
- ~ Licenses of applicants for positions requiring licensure

are verified prior to employment and that there is documentation that licenses are kept current.

6.6 TRAINING AND TECHNICAL ASSISTANCE

Projects must provide for the orientation and in-service training of all project personnel, including the staffs of delegate agencies and service sites. All project personnel should participate in continuing education related to their activities. Documentation of continuing education should be maintained and used in evaluating the scope and effectiveness of the staff training program.

Training through regional training centers is available to all projects under the Title X program. In addition to training, grantees may receive technical assistance for specific project activities. Technical assistance is provided by contract from the OPA and administered through the Regional Office. Information on training and technical assistance is available from the Regional Office.

6.7 REPORTING REQUIREMENTS

Grantees must:

- (1) comply with the financial and other reporting requirements of 45 CFR Part 74 or 45 CFR Part 92, as applicable; and
- (2) comply with other reporting requirements as required by DHHS.

6.8 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members (the size of the committee can differ from these limits with written documentation and approval from the Regional Office) who are broadly representative of the community must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X. Oversight responsibility for the I&E committee(s) rests with the grantee. The grantee may delegate the I & E operations for the review and approval of materials to delegate/contract agencies.

The I&E committee(s) must:

- ~ Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- ~ Consider the standards of the population or community to be served with respect to such materials;
- ~ Review the content of the material to assure that the information is factually correct;

- ~ Determine whether the material is suitable for the population or community to which it is to be made available; and

- ~ Establish a written record of its determinations [59.6].

The committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff. However, final approval of the I& E material rests with the committee(s).

6.9 COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

Boards and advisory committees for family planning services should be broadly representative of the population served.

~ Community Participation

Title X grantees and delegate/contract agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services [59.5(b)(10)].

The I& E advisory committee may serve the community participation function if it meets the above requirements, or a separate group may be identified. In either case, the grantee project plan must include a plan for community participation. The community participation committee must meet annually or more often as appropriate.

~ Community Education

Each family planning project must provide for community education programs [59.5(b)(3)]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial.

~ Project Promotion

To facilitate community awareness of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community [59.5(b)(3)]. Projects should review a range of strategies and assess the availability of existing resources and materials. Promotion activities should be reviewed annually and be responsive to the changing needs of the community. For more information, contact the Regional Offices.

6.10 PUBLICATIONS AND COPYRIGHT

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. The word "publication" is defined to include computer software. Grantees should ensure that publications developed under Title X do not contain information which is contrary to program requirements or to accepted clinical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the Public Health Service Grants Policy Statement. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable right of the Government to reproduce, publish, or otherwise use such materials for Federal purposes and to authorize others to do so [45 CFR 74.36][45 CFR 92.34].

6.11 INVENTIONS OR DISCOVERIES

Family planning projects must comply with Government-wide regulations, 37 CFR Part 401, which apply to the rights to inventions made under government grants, contracts and cooperative agreements.

PART II

7.0 Client Services

Projects funded under Title X must provide clinical, informational, educational, social and referral services relating to family planning to clients who want such services. All projects must offer a broad range of acceptable and effective medically approved family planning methods and services either on-site or by referral [59.5(a)(1)]. Projects should make available to clients all methods of contraception approved by the Federal Food and Drug Administration.

Part II of this document has been developed to assist grantees in determining those services which will be provided to fulfill the mission of Title X.

- ~ Projects must provide services stipulated in the law or regulations, or which are required by these Guidelines for the provision of high quality family planning services.
- ~ Projects may also provide those services that are intended to promote the reproductive and general health care of the family planning client population.

7.1 SERVICE PLANS AND PROTOCOLS

The service plan is the component of the grantee's project plan, as set forth in the competitive application, which identifies those services to be provided to clients under Title X by the project. As part of the project plan, all grantees must assure that delegate/contractors have written clinical protocols and plans for client education, approved by the grantee and signed by the service site Medical Director, which outline procedures for the provision of each service offered and which are in accordance with state

laws. Clinical protocols must be consistent with the requirements of these Guidelines.

Under exceptional circumstances, a waiver from a particular requirement may be obtained from the Regional Office upon written request from a grantee. In submitting a request for an exception, the grantee must provide epidemiologic, clinical, and other supportive data to justify the request and the duration of the waiver.

7.2 PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. However, the following components must be offered to and documented on all clients at the initial visit:

Education

- ~ Presentation of relevant information and educational materials, based upon client needs and knowledge;

Counseling

- ~ Interactive process in which a client is assisted in making an informed choice;

Informed Consent

- ~ Explanation of all procedures and obtaining a general consent covering examination and treatment and, where applicable, a method specific informed consent form;

History

- ~ Obtaining of a personal and family medical and social history;

Examination

- ~ Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

- ~ Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

- ~ Planned mechanism for client follow-up;
- ~ Performance of any necessary clinical procedures;
- ~ Provision of medications and/or supplies as needed; and
- ~ Provision of referrals as needed.

Return visits, with the exception of routine supply visits, should include an assessment of the client's health status, current complaints, and evaluation of birth control method, as well as an opportunity to change methods. The following components must be offered to and documented on all clients at the return visit:

History

- ~ Updating a personal and family medical and social history;

Examination

- ~ Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

- ~ Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

- ~ Planned mechanism for client follow-up;
- ~ Performance of any necessary clinical procedures;
- ~ Provision of medications and/or supplies as needed; and
- ~ Provision of referrals as needed.

7.3 EMERGENCIES

Emergency situations involving clients and/or staff may occur at any time. All projects must therefore have written plans for the management of on-site medical emergencies. At a minimum, written protocols must address vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties. Protocols must also be in place for emergencies requiring transport, after-hours management of contraceptive emergencies, and clinic emergencies. All project staff must be familiar with these plans. Appropriate training, including training in CPR, should be available to staff.

7.4 REFERRALS AND FOLLOW-UP

Grantees must assure that delegate/contract agencies provide all family planning services listed in Section 8.0 under "Required Services," either on-site or by referral. When required services are to be provided by referral, the grantee must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.

Agencies must have written policies/procedures for follow-up on referrals that are made as a result of abnormal physical examination or laboratory test findings. These policies must be sensitive to clients' concerns for confidentiality and privacy.

For services determined to be necessary but which are beyond the scope of the project, clients must be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies must:

- ~ Make arrangements for the provision of pertinent client information to the referral provider. Agencies must obtain client's consent to such arrangements, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality;
- ~ Advise client on their responsibility in complying with the referral; and
- ~ Counsel client on the importance of such referral and the agreed upon method of follow-up.

Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care. Agencies must maintain a current list of health care providers, local health and human services departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs to be used for referral purposes. Whenever possible, clients should be given a choice of providers from which to select.

8.0 Required Services

The services contained in this section must be provided by all projects funded under Title X.

The client's written informed voluntary consent to receive services must be obtained prior to the client receiving any clinical services. In addition, if a client chooses a prescription method of contraception, a method-specific consent form must be obtained and updated routinely at subsequent visits to reflect current information about that method.

8.1 CLIENT EDUCATION

Grantees and/or delegate/contract agencies must have written plans for client education that include goals and content outlines to ensure consistency and accuracy of information provided. Client education must be documented in the client record. The education provided should be appropriate to the client's age, level of knowledge, language, and socio-cultural background and be presented in an unbiased manner. A mechanism to determine that the information provided has been understood should be established.

Education services must provide clients with the information needed to:

- ~ Make informed decisions about family planning;
- ~ Use specific methods of contraception and identify adverse effects;
- ~ Perform breast/testicular self examination;
- ~ Reduce risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV);
- ~ Understand the range of available services and the purpose and sequence of clinic procedures; and

- ~ Understand the importance of recommended screening tests and other procedures involved in the family planning visit.

Clients should be offered information about basic female and male reproductive anatomy and physiology, and the value of fertility regulation in maintaining individual and family health. Additional education should include information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse.

~ Method-Specific Informed Consent

Written informed consent, specific to the contraceptive method, must be signed before a prescription contraceptive method is provided. Prior to implementation, informed consent forms should be approved by the service site Medical Director.

The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen. Specific education and consent forms for the contraceptive method provided must be part of the project's service plan.

The signed informed consent form must be a part of the client's record. All consent forms should contain a statement that the client has been counseled, provided with the appropriate informational material, and understands the content of both. The method-specific consent form should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method.

Federal sterilization regulations [42 CFR Part 50, Subpart B], which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.2 COUNSELING

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware and able to create an environment in which the client feels comfortable discussing personal information. The counselor must be sufficiently knowledgeable to provide accurate information regarding the benefits and risk, safety, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the various contraceptive methods.

Additionally, the counselor should be knowledgeable about the other services offered by the agency. Documentation of counseling must be included in the client's record.

~ Method Counseling

Method counseling refers to an individualized dialogue with a client that covers the following:

- ~ Results of physical exam and lab studies;
- ~ Effective use of contraceptive methods, including natural family planning (NFP), and the benefit and efficacy of the methods;
- ~ Possible side effects/complications;
- ~ How to discontinue the method selected and information regarding back-up method use, including the use of certain oral contraceptives as post-coital emergency contraception;
- ~ Planned return schedule;
- ~ Emergency 24-hour telephone number;
- ~ Location where emergency services can be obtained; and
- ~ Appropriate referral for additional services as needed.

~ Sexually Transmitted Disease (STD) and HIV Counseling

All clients must receive thorough and accurate counseling on STDs and HIV. STD/HIV counseling refers to an individualized dialogue with a client in which there is discussion of personal risks for STDs/HIV, and the steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STD/HIV must be given advice regarding risk reduction and must be advised whether clinical evaluation is indicated. All projects must offer, at a minimum, education about HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may also provide HIV risk assessment, counseling and testing by specially trained staff. When the project does not offer these optional services, the project must provide the client with a list of health care providers who can provide these services.

8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING

~ History

At the initial comprehensive clinical visit, a complete medical history must be obtained on all female and male clients. Pertinent history must be updated at subsequent clinical visits. The comprehensive medical history must address at least the following areas:

- ~ Significant illnesses; hospitalizations; surgery; blood transfusion or exposure to blood products; and chronic or acute medical conditions;
- ~ Allergies;
- ~ Current use of prescription and over-the-counter medications;
- ~ Extent of use of tobacco, alcohol, and other drugs;
- ~ Immunization and Rubella status;
- ~ Review of systems;
- ~ Pertinent history of immediate family members; and
- ~ Partner history
 - injectable drug use
 - multiple partners
 - risk history for STDs and HIV
 - bisexuality.

Histories of reproductive function in female clients must include at least the following:

- ~ Contraceptive use past and current (including adverse effects);
- ~ Menstrual history;
- ~ Sexual history;
- ~ Obstetrical history;
- ~ Gynecological conditions;
- ~ Sexually transmitted diseases, including HBV;
- ~ HIV;
- ~ Pap smear history (date of last Pap, any abnormal Pap, treatment); and
- ~ In utero exposure to diethylstilbestrol (DES).

Histories of reproductive function in male clients must include at least the following:

- ~ Sexual history;
- ~ Sexually transmitted diseases (including HBV);

~ HIV; and

~ Urological conditions.

~ Physical Assessment (female)

For many clients, family planning programs are their only continuing source of health information and clinical care. Therefore, an initial complete physical examination, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts, abdomen, pelvis, and rectum, should be performed.

While most client services will necessarily relate to fertility regulation, family planning clinics must provide and encourage clients to use health maintenance screening procedures, initially and as indicated. Clinics must provide and stress the importance of the following to all clients:

- ~ Blood pressure evaluation;
- ~ Breast exam;
- ~ Pelvic examination which includes vulvar evaluation and bimanual exam;
- ~ Pap smear;
- ~ Colo-rectal cancer screening in individuals over 40; and
- ~ STD and HIV screening, as indicated.

Following counseling about the importance of the above preventive services, if a client chooses to decline or defer a service, this should be documented in their record. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or procedures.

All physical examination and laboratory test requirements stipulated in the prescribing information for specific methods of contraception must be followed. Physical examination and related prevention services should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless if in the clinician's judgment there is a compelling reason for extending the deferral. All deferrals, including the reason(s) for deferral, must be documented in the client record. Project protocols should be developed accordingly.

~ Physical Assessment (male)

Family planning clinics also may be an important source of reproductive health care for male clients. Physical examination should be made available to male clients, including height and weight, examination of the thyroid, heart, lungs, breasts, abdomen, extremities, genitals and rectum.

Examination should also include palpation of the prostate, as appropriate, and instructions in self-examination of the testes. Clinics should stress the importance of the following to male clients:

- ~ Blood pressure evaluation;
- ~ Colo-rectal cancer screening in individuals over 40; and
- ~ STD and HIV screening, as indicated.

~ Laboratory Testing

Specific laboratory tests are required for the provision of specific methods of contraception. Laboratory tests can also be important indicators of client health status and useful for diagnostic purposes. Pregnancy testing must be provided onsite. The following laboratory procedures must be provided to clients if required in the provision of a contraceptive method, and may be provided for the maintenance of health status and/or diagnostic purposes, either on-site or by referral:

- Anemia assessment
- Gonorrhea and chlamydia test
- Vaginal wetmount
- Diabetes testing
- Cholesterol and lipids
- Hepatitis B testing
- Syphilis serology (VDRL, RPR)
- Rubella titer
- Urinalysis
- HIV testing

~ Notification of Abnormal Lab Results

A procedure which addresses client confidentiality must be established to allow for client notification and adequate follow-up of abnormal laboratory results.

~ Other Laboratory Services or Procedures

Other procedures and lab tests may be indicated for some clients and may be provided on-site or by referral.

~ Revisits

Revisit schedules must be individualized based upon the client's need for education, counseling, and clinical care beyond that provided at the initial and annual visit.

Clients selecting hormonal contraceptives, intrauterine devices (IUDs), cervical caps, or diaphragms for the first time should be scheduled for a revisit as appropriate after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information or clarification. A new or established client who chooses to continue a method already in use need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

8.4 FERTILITY REGULATION

~ Reversible Contraception

Currently, the reversible methods of contraception include barrier methods (female and male), IUDs, fertility awareness methods, natural family planning, and hormonal methods (injectables, implants, orals). Certain oral contraceptive regimens have been found by the Federal Food and Drug Administration to be safe and effective for use as postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. More than one method of contraception can be used simultaneously by a client and may be particularly indicated to minimize the risks of STDs/HIV and pregnancy. Consistent and correct use of condoms should be encouraged for all persons at risk for STDs/HIV.

~ Permanent Contraception

The counseling and consent process must assure that the client's decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal sterilization regulations, which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.5 INFERTILITY SERVICES

Grantees must make basic infertility services available to women and men desiring such services. Infertility services are categorized as follows:

- | | |
|-----------|--|
| Level I | Includes initial infertility interview, education, physical examination, counseling, and appropriate referral. |
| Level II | Includes such testing as semen analysis, assessment of ovulatory function and postcoital testing. |
| Level III | More sophisticated and complex than Level I and Level II services. |

Grantees must provide Level I infertility services as a minimum. Level II infertility services may be offered in projects with clinicians who have special training in infertility. Level III services are considered to be beyond the scope of Title X program.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Projects must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to the family planning facility. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects should have available a pregnancy test of high sensitivity. If the medical examination cannot be performed in conjunction with the laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, referral for early initiation of prenatal care should be made. Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays). For clients with a negative pregnancy diagnosis, the cause of delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.

Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- ~ Prenatal care and delivery;
- ~ Infant care, foster care, or adoption; and
- ~ Pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling [59.5(a)(5)].

Clients who are found not to be pregnant should be given information about the availability of contraceptive and infertility services, as appropriate.

8.7 ADOLESCENT SERVICES

Adolescent clients require skilled counseling and age-appropriate information. Appointments should be available to them for counseling and clinical services as soon as possible.

Adolescents seeking contraceptive services must be informed about all methods of contraception. Abstinence as well as contraceptive and safer sex practice

options to reduce risks for STD/HIV and pregnancy must be discussed with all adolescents. It is important not to assume that adolescents are sexually active simply because they have come for family planning services. As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively.

Adolescents must be assured that the counseling sessions are confidential and, if follow-up is necessary, every attempt will be made to assure the privacy of the individual. However, counselors should encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on resisting attempts to coerce minors into engaging in sexual activities. Title X projects may not require written consent of parents or guardians for the provision of services to minors. Nor can the project notify parents or guardians before or after a minor has requested and received Title X family planning services.

8.8 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

The children of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. As part of the medical history, clients born between 1940 and 1970 should be asked if their mothers took estrogens during pregnancy. Clients prenatally exposed to exogenous estrogens should receive information/education and special screening either on-site or by referral.

9.0 Related Services

The following related health services, which can improve quality of care, may be offered if skilled personnel and equipment are available.

9.1 GYNECOLOGIC SERVICES

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of health care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine. More complex procedures, such as colposcopy, may be offered, provided that clinicians performing these services have specialized training.

9.2 SEXUALLY TRANSMITTED DISEASES (STD) AND HIV/AIDS

The increasing incidence and prevalence of STDs, particularly among adolescents, requires that family planning projects increase their efforts to provide education and information about the more common STDs and HIV/AIDS. Projects should make available detection and treatment of the more common STDs. At-risk clients should be urged to undergo examination and treatment as indicated, either directly or by referral. When treatment is provided on-site, appropriate follow-up measures must be undertaken.

Gonorrhea and chlamydia tests must be available for clients requesting IUD insertion. Tests for gonorrhea, syphilis, chlamydia and HIV should be provided as indicated by client request or evidence of increased risk for infection.

Grantees and/or delegate contract agencies must comply with state and local STD reporting requirements.

9.3 SPECIAL COUNSELING

Clients should be offered appropriate counseling and referral as indicated regarding future planned pregnancies, management of a current pregnancy, and other individual concerns (e.g., substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) as indicated. Preconceptional counseling should be provided if the client's history indicates a desired pregnancy in the future.

9.4 GENETIC INFORMATION AND REFERRAL

Basic information regarding genetic conditions should be offered to family planning clients who request or are in need of such services. Extensive genetic counseling and evaluation is beyond the scope of the Title X program. Referral systems should be in place for those who require further genetic counseling and evaluation

9.5 HEALTH PROMOTION/DISEASE PREVENTION

Family planning programs should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease. Programs are encouraged to assess the health problems prevalent in the populations they serve and to develop strategies to address them.

9.6 POSTPARTUM CARE

Family planning programs may provide postpartum care in collaboration with local agencies or institutions which provide prenatal and/or intrapartum care. If a family planning program undertakes responsibility for postpartum care, such care should be directed toward assessment of the woman's physical health, initiation of contraception if desired, and counseling and education related to parenting, breast feeding, infant care, and family adjustment.

10.0 Clinic Management

10.1 EQUIPMENT AND SUPPLIES

Equipment and supplies must be appropriate to the type of care offered by the project. Projects are expected to follow applicable Federal and state regulations regarding infection control.

10.2 PHARMACEUTICALS

Agencies must be operated in accordance with Federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project.

10.3 MEDICAL RECORDS

Projects must establish a medical record for every client who obtains clinical services. These records must be maintained in accordance with

accepted medical standards and State laws with regard to record retention. Records must be:

- ~ Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;
- ~ Signed by the clinician and other appropriately trained health professionals making entries, including name, title and date;
- ~ Readily accessible;
- ~ Systematically organized to facilitate prompt retrieval and compilation of information;
- ~ Confidential;
- ~ Safeguarded against loss or use by unauthorized persons;
- ~ Secured by lock when not in use; and
- ~ Available upon request to the client.

~ Content of the Client Record

The client's medical record must contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical impression or diagnosis, and warrant the treatment and end results. The required content of the medical record includes:

- ~ Personal data;
- ~ Medical history, physical exam, laboratory test orders, results, and follow-up;
- ~ Treatment and special instructions;
- ~ Scheduled revisits;
- ~ Informed consents;
- ~ Refusal of services; and
- ~ Allergies and untoward reactions to drug(s) recorded in a prominent and specific location.

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral, and follow-up. The record must allow for entries by counseling and social service staff. Projects should maintain a problem list at the front of each chart listing identified problems to facilitate

continuing evaluation and follow-up. Client financial information should be kept separate from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.

~ Confidentiality and Release of Records

A confidentiality assurance statement must appear in the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality [59.11]. HIV information should be handled according to law, and kept separate whenever possible. When information is requested, agencies should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care.

10.4 QUALITY ASSURANCE AND AUDIT

A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality assurance system should include:

- ~ An established set of clinical, administrative and programmatic standards by which conformity would be maintained;
- ~ A tracking system to identify clients in need of follow-up and/or continuing care;
- ~ Ongoing medical audits to determine conformity with agency protocols;
- ~ Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;
- ~ Periodic review of medical protocols to insure maintenance of current standards of care;
- ~ A process to elicit consumer feedback; and
- ~ Ongoing and systematic documentation of quality assurance activities.

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[Notices]
[Page 41281-41282]
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[[Page 41281]]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science

Provision of Abortion-Related Services in Family Planning
Services Projects

AGENCY: Office of Population Affairs, OPHS, DHHS.

ACTION: Notice.

SUMMARY: This notice informs the public of the interpretations relating to the statutory requirement that no funds appropriated under Title X of the Public Health Service Act be used in programs in which abortion is a method of family planning.

FOR FURTHER INFORMATION CONTACT: Samuel S. Taylor, Office of Population Affairs, (301) 594-4001.

SUPPLEMENTARY INFORMATION: On February 5, 1993, the Department of Health and Human Services published in the Federal Register a notice of proposed rulemaking that proposed to revise the regulations at 42 CFR Part 59, Subpart A. Subpart A of Part 59 sets forth the program requirements applicable to grantees under section 1001 of the Public Health Service (PHS) Act, 42 U.S.C. 300, et seq. The notice of proposed rulemaking proposed to revise that subpart by readopting the program regulations as they existed prior to February 2, 1988. This action would have the effect of revoking the regulations published on February 2, 1988, commonly known as the ``Gag Rule,'' which set forth standards for the compliance by such grantees with section 1008 of that Act, 42 U.S.C. 300a-6.

The February 5, 1993 notice of proposed rulemaking also proposed to reinstitute the pre-1988 policies and interpretations regarding compliance with section 1008. 58 FR 7464. As explained in the notice of proposed rulemaking, those policies and interpretations derived from previous opinions of the Department concerning section 1008. To promote more useful public comment in the rulemaking process, the Department subsequently made available a more detailed summary of the policies and interpretations and reopened the public comment period. 58 FR 34042 (June 23, 1993).

A number of public comments on the prior policies and interpretations were obtained during the reopened comment period, and the public comments received during both comment periods were generally focused on the prior policies and interpretations rather than on the

proposed regulatory language. The Department has changed one paragraph of the regulations and has modified its prior interpretations in several particulars based in part on the public comment received. These modifications, and the grounds therefor, are described in the preamble to the final rules published on this date in the rules section of the Federal Register. The interpretations, as so modified, are set out in the summary statement below. The summary below is also reorganized from the summary statement made available for public comment, for purposes of clarification.

Accordingly, to provide guidance to grantees in order to promote uniform administration of the program and facilitate grantee compliance with the interpretations that are being reinstituted in conjunction with the final regulations adopted on this date, provided below is a summary of the program regulatory requirements and interpretations that relate to section 1008 of the PHS Act.

Program Policies Regarding the Title X National Family Planning Program and the Section 1008 Abortion Prohibition

Section 1008 of the Title X statute, 42 U.S.C. 300a-6, states: ``None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.'' This prohibition applies not only to the performance of abortion by a Title X project, but also to the conduct of certain abortion-related activities by the project. However, the prohibition does not apply to all the activities of a Title X grantee, but only to those within the Title X project. This statement summarizes the Department requirements and interpretations in existence prior to the imposition of the 1988 ``Gag Rule'' with regard to implementation of section 1008, as modified following the rulemaking of 1993.

1. General Principles

In general, section 1008 prohibits Title X programs from engaging in activities which promote or encourage abortion as a method of family planning. However, section 1008 does not prohibit the funding under Title X of activities which have only a possibility of encouraging or promoting abortion; rather, a more direct nexus is required. The general test is whether the immediate effect of the activity in question is to promote or encourage the use of abortion as a method of family planning. If the immediate effect of the activity in question is essentially neutral, then it is not prohibited by the statute. Thus, a Title X project may not provide services that directly facilitate the use of abortion as a method of family planning, such as providing transportation for an abortion, explaining and obtaining signed abortion consent forms from clients interested in abortions, negotiating a reduction in fees for an abortion, and scheduling or arranging for the performance of an abortion, promoting or advocating abortion within Title X program activities, or failing to preserve sufficient separation between Title X program activities and abortion-related activities.

2. Abortion Counseling and Referral

Under 42 CFR 59.5(a)(5), a Title X project must:

Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- (A) Prenatal care and delivery;
- (B) Infant care, foster care, or adoption; and
- (C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral on request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

However, there are limitations on what abortion counseling and referral is permissible under the statute. A Title X project may not provide pregnancy options counseling which promotes abortion or encourages persons to obtain abortion, although the project may provide patients with complete factual information about all medical options and the accompanying risks and benefits. While a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient. Where a referral to another provider who might perform an abortion is medically indicated because of the patient's condition or the condition of the fetus (such as where the woman's life would be endangered), such a referral by a Title X project is not prohibited by section 1008 and is required by 42 CFR 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications.

[[Page 41282]]

3. Advocacy Activities

A Title X project may not promote or encourage the use of abortion as a method of family planning through advocacy activities such as providing speakers to debate in opposition to anti-abortion speakers, bringing legal action to liberalize statutes relating to abortion, or producing and/or showing films that encourage or promote a favorable attitude toward abortion as a method of family planning. Films that present only neutral, factual information about abortion are permissible. A Title X project may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project). A Title X project may also discuss abortion as an available alternative when a family planning method fails in a discussion of relative risks of various methods of contraception.

4. Separation

Non-Title X abortion activities must be separate and distinct from Title X project activities. Where a grantee conducts abortion activities that are not part of the Title X project and would not be permissible if they were, the grantee must ensure that the Title X-supported project is separate and distinguishable from those other activities. What must be looked at is whether the abortion element in a program of family planning services is so large and so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost.

The Title X project is the set of activities the grantee agreed to perform in the relevant grant documents as a condition of receiving Title X funds. A grant applicant may include both project and nonproject activities in its grant application, and, so long as these are properly distinguished from each other and prohibited activities are not reflected in the amount of the total approved budget, no problem is created. Separation of Title X from abortion activities does not require separate grantees or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008.

Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities: (a) A common waiting room is permissible, as long as the costs properly pro-rated; (b) common staff is permissible, so long as salaries are properly allocated and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project; (c) a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project; and (d) maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated.

Whether a violation of section 1008 has occurred is determined by whether the prohibited activity is part of the funded project, not by whether it has been paid for by federal or non-federal funds. A grantee may demonstrate that prohibited abortion-related activities are not part of the Title X project by various means, including counseling and service protocols, intake and referral procedures, material review procedures, and other administrative procedures.

Dated: June 28, 2000.
Samuel S. Taylor,
Acting Director, Office of Population Affairs.
[FR Doc. 00-16759 Filed 6-30-00; 8:45 am]
BILLING CODE 4160-17-M

REGION VII INFERTILITY PREVENTION PROJECT (IPP) (IA, KS, MO, NE)

CHLAMYDIA SCREENING GUIDELINES (TESTS SENT TO NEBRASKA PUBLIC HEALTH LABORATORY)

For

FAMILY PLANNING SITES, COMMUNITY HEALTH CENTERS,
STUDENT HEALTH CLINICS AND PRIVATE PHYSICIANS

All Women 10 - 24 Years of age

All Women 25 - 29 Years Old with ONE of the following Risk Factors:

- New Partner or Multiple Partners in Last 90 days.
- Recent Contact to Male with Urethritis, Known Chlamydia
OR other STD
- Clinical signs suggestive of Chlamydia Infection: Cervicitis,
MUCOPUS, CERVICAL FRIABILITY, PID

*A test of cure is not recommended. If you suspect reinfection; you must wait for
at least three weeks after treatment is completed before retesting.*

- ◆ To test women 25 years old or older without a risk factor, set up a separate account with the Nebraska Public Health Lab. The lab will bill you for those tests. Or send the specimen to another lab.
- ◆ Women over 30 years old may be presumptively treated.
- ◆ To test women over 30 years old, set up a private account with the Nebraska Public Health Lab. The lab will bill you for those tests. Or send the specimen to a different lab.

CDC RECOMMENDED TREATMENT GUIDELINES FOR CHLAMYDIA

RECOMMENDED REGIMENS:

- ✓ Azithromycin 1 gm Orally in a Single Dose (*safety/efficacy in pregnancy has not been established*) **or**
- ✓ Doxycycline 100 mg Orally 2 Times a Day for 7 Days (*contraindicated for pregnant or lactating women and for adolescents ≤ 17*)

ALTERNATIVE REGIMENS:

For Pregnant or lactating women and adolescents age 17 or less:

- ✓ Erythromycin Base 500 mg Orally 4 Times a Day for 7 Days **or**
- ✓ Erythromycin ethylsuccinate 800 mg Orally 4 Times a Day for 7 Days

Contraindicated for pregnant or lactating women and adolescents age 17 or less:

- ✓ Ofloxacin 300 mg Orally 2 Times a Day for 7 Days **or**
- ✓ Levofloxacin 500 mg Orally for 7 Days

IF ABOVE REGIMENS NOT TOLERATED:

- ✓ Erythromycin Base 250 mg Orally 4 Times a Day for 14 Days **or**
- ✓ Erythromycin ethylsuccinate 400 mg Orally 4 Times a Day for 14 Days

Note: Erythromycin estolate is Contraindicated in Pregnancy

TREATMENT FOR GONORRHEA

RECOMMENDED REGIMENS:

- ✓ Cefixime 400 mg Orally in a Single Dose **or**
- ✓ Ceftriaxone 125 mg IM in a Single Dose **or**
- ✓ Ciprofloxacin 500 mg Orally in a Single Dose (*contraindicated for pregnant or lactating women and for adolescents ≤ 17*) **or**
- ✓ Ofloxacin 400 mg Orally in a Single Dose (*contraindicated for pregnant or lactating women and for adolescents ≤ 17*) **or**
- ✓ Levofloxacin 250 mg in a Single Dose (*contraindicated for pregnant or lactating women and for adolescents ≤ 17*)

Because coinfection with *C. trachomatis* is common, persons treated for gonorrhea should also be treated presumptively with a regimen that is effective against *C. trachomatis*.

SUBGRANT TERMS AND ASSURANCES
Nebraska Health and Human Services System (NHHSS)
Department of Health and Human Services Regulation and Licensure (HHS R&L)
Title X Family Planning Services

Three agencies comprise NHHSS. The Department of Health and Human Services, Department of Health and Human Services Regulation and Licensure, and Department of Health and Human Services Finance and Support are referred collectively as the **Nebraska Health and Human Services System**.

This is a subgrant of federal financial assistance. By accepting this subgrant, the Subrecipient agrees to comply with the terms and conditions described herein.

SECTION I. OPERATIONAL TERMS AND ASSURANCES

- A. Programs. Subrecipient must operate the program(s) in compliance with the documents governing the award. The following documents and any revisions made during the program period govern the Subgrant and are hereby incorporated by this reference as though fully set forth herein.
- 1) Nebraska Health & Human Services System (NHHSS) Request for Proposals;
 - 2) Subrecipient Project(s) Proposal;
 - 3) Subrecipient Reporting Requirements (Exhibit 1);
 - 4) Program Specific Requirements (Exhibit 2);
 - 5) NHHSS Administrative and Audit Guidance for Subgrants (Exhibit 3) and the attached certifications; and
 - 6) NHHSS' letter of award which includes the award period, amount of funds awarded, and any contingencies to the Subgrant award.
- B. Reports. Subrecipient must submit data, program, and financial reports according to the reporting requirements (Exhibit 1). Extensions for the submission of reports and reimbursement **must be submitted in writing** to NHHSS for approval to prevent withholding of payment.
- C. Administrative Requirements. Subrecipient must perform Subgrant activities, expend funds, and report financial and program activities in accordance with Federal grants administration regulations, U.S. Office of Management and Budget Circulars governing cost principles and audits (Exhibit 3), and comply with, complete, and return the certifications attached hereto.
- D. Program Specific Requirements. Subgrant activities must comply with any program specific requirements included in NHHSS' Request for Application and Exhibit 2.

E. Payments. Subrecipient will be paid in advance, provided they maintain or demonstrate the willingness and ability to maintain procedures to minimize the time elapsing between the transfer of the funds and their disbursement, in accordance with 45CFR29§92.21. NHHSS will make payments subject to the following conditions:

- 1) Subrecipient's submission of reports according to the reporting requirements described in Exhibit 1.
- 2) Availability of governmental funds to support this project. In the event funds cease to be available, this Subgrant shall be terminated, or the activities shall be suspended until such funds become available, in the sole discretion of NHHSS.
- 3) Pursuant to the Nebraska Prompt Payment Act.
- 4) Suspension or termination for cause or convenience as described in the federal grants administration regulations applicable to the Subrecipient.

F. Budget Changes. The Subrecipient is permitted to reassign funds from one line item to another line item within the approved budget. Prior approval by NHHSS is not required **provided** the cumulative transfers do not exceed ten percent of the total approved budget, are for an allowable cost allocable to the Subgrant, do not add or eliminate a line item and do not result in programmatic changes.

Prior approval is **required** for cumulative budget transfers exceeding ten percent of the current total approved budget. Requests for transfers shall be addressed in writing to NHHSS. NHHSS shall approve or disapprove the request in writing within 30 days of its receipt.

G. Programmatic changes. The Subrecipient shall request in writing NHHSS approval for programmatic changes. NHHSS shall send a written determination regarding the request to the Subrecipient within 30 days of its receipt.

H. Technical Assistance. NHHSS will provide training and materials, procedures, assistance with quality assurance procedures, and site visits by representatives of NHHSS and the federal granting agency in order to review program accomplishments, evaluate management control systems and other technical assistance as needed or requested.

I. Subrecipient Procurement. Subrecipient shall be the responsible authority regarding the settlement and satisfaction of all contractual and administrative issues, without recourse to NHHSS, arising out of procurement entered into by it in connection with the subgrant. Such issues include, but are not limited to, disputes, claims, protests of award, source evaluation and other matters of a contractual nature.

J. Subgrant Close-out. Upon the expiration or notice of termination of this Subgrant, the following procedures shall apply for close-out of the subgrant:

- 1) Upon request from Subrecipient, any allowable reimbursable cost not covered by previous payments shall be paid by NHHSS

- 2) Subrecipient shall make no further disbursement of funds paid to Subrecipient, except to meet expenses incurred on or prior to the termination or expiration date, and shall cancel as many outstanding obligations as possible. NHHSS shall give full credit to Subrecipient for the federal share of non-cancelable obligations properly incurred by Subrecipient prior to termination.
- 3) Subrecipient shall immediately return to NHHSS any unobligated balance of cash advanced or shall manage such balance in accordance with NHHSS instructions.
- 4) Within a maximum of 90 days following the date of expiration or termination, Subrecipient shall submit all financial, performance, and related reports required by the terms of the Agreement to NHHSS. NHHSS reserves the right to extend the due date for any report and may waive, in writing, any report it considers to be unnecessary.
- 5) NHHSS shall make any necessary adjustments upward or downward in the federal share of costs.
- 6) The Subrecipient shall assist and cooperate in the orderly transition and transfer of subgrant activities and operations with the objective of preventing disruption of services.
- 7) Close-out of this Subgrant shall not affect the retention period for, or state or federal rights of access to, Subrecipient records. Nor shall close-out of this Subgrant affect the Subrecipient's responsibilities regarding property or with respect to any program income for which Subrecipient is still accountable under this Subgrant. If no final audit is conducted prior to close-out, NHHSS reserves the right to disallow and recover an appropriate amount after fully considering any recommended disallowances resulting from an audit which may be conducted at a later time.

SECTION II. GENERAL TERMS AND ASSURANCES

A. Documents Incorporated by Reference. All laws, rules, regulations, guidelines, directives and documents, attachments, appendices, and exhibits referred to in these terms and assurances shall be deemed incorporated by this reference and made a part of this Subgrant as though fully set forth herein.

B. Independent Legal Entity. The Subrecipient is an independent legal entity and neither it nor any of its employees shall be deemed employees of NHHSS for any purpose. The Subrecipient shall employ and direct such personnel as it requires to perform its obligations under this Subgrant, shall exercise full authority over its personnel, and shall comply with all worker's compensation, employer's liability, and other federal, state, county, and municipal laws, ordinances, rules, and regulations required of an employer providing services as contemplated by this Subgrant.

C. Release and Indemnity.

- 1) The Subrecipient shall assume all risk of loss and hold NHHSS, its employees, agents, assignees and legal representatives harmless from all liabilities, demands, claims, suits,

losses, damages, causes of action, fines or judgments and all expenses incident thereto, for injuries to persons and for loss of, damage to, or destruction of property arising out of or in connection with this grant, and proximately caused by the negligent or intentional acts or omissions of the Subrecipient, its officers, employees or agents; for any losses caused by failure by the Subrecipient to comply with terms and conditions of the grant; and, for any losses caused by other parties which have entered into agreements with the Subrecipient.

- 2) The NHHSS, if liable, is limited to the extent provided by the Nebraska Tort Claims Act, and the Nebraska Miscellaneous Claims Act; and any other applicable provisions of law. The NHHSSR&L does not assume liability for the action of its Contractors.

D. Drug-Free Work-Place Policy. The Subrecipient hereby assures NHHSS that it will operate a drug-free workplace in accordance with State and federal guidelines and has implemented a drug-free workplace policy which is available to the NHHSS upon request.

E. Acknowledgment of Support. Publications by the Subrecipient, including news releases and articles, shall acknowledge the financial support of NHHSS and the federal granting agency by including a statement therein that, **"This project is supported in part by federal Title X Family Planning Services and Title V Maternal and Child Health Block Grant funds awarded to the (Subrecipient) by the Nebraska Health and Human Services System."**

F. Data Ownership and Copyright. All data collected as a result of this project shall be the property of the NHHSS. The Subrecipient may copyright any of the copyrightable material produced in conjunction with the performance required under this Subgrant. The NHHSS hereby reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use the copyrightable material for State purposes.

G. Notices. All notices given under the terms of this Subgrant shall be sent by United States mail, postage prepaid, addressed to the respective party at the address set forth on the signature page hereof, or to such other addresses as the parties shall designate in writing from time to time.

H. Authorized Official. The person executing the Proposal Cover Sheet is an official of the Subrecipient who has the authority to bind the Subrecipient to the terms and assurances of this Subgrant of federal financial assistance.

I. Public Counsel. In the event the Subrecipient provides health and human services to individuals on behalf of NHHSS under the terms of this Subgrant, Subrecipient shall submit to the jurisdiction of the Public Counsel under Neb. Rev. Stat. §§81-8,240 to 81-8,254 with respect to the provision of services under this subgrant. This clause shall not apply to grants or contracts between NHHSS and long-term care facilities subject to the jurisdiction of the state long-term care ombudsman pursuant to the Long-Term Care Ombudsman Act.

J. Nondiscrimination. The Subrecipient acknowledges that the Subgrant activities must be operated in compliance with civil rights laws and any implementing regulations, and makes the following assurances.

The Recipient warrants and assures that it complies as applicable to it with Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of

1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act of 1990, to the effect that no person shall, on the grounds of race, color, national origin, sex, age, handicap or disability, be excluded from participation in, denied benefits of, or otherwise be subjected to discrimination under any program or activity of the Subrecipient.

The Subrecipient and any of its subcontractors shall not discriminate against any employee or applicant for employment, to be employed in the performance of this grant with respect to hire, tenure, terms, conditions or privileges of employment because of the race, color, religion, sex, disability or national origin of the employee or applicant. The Subrecipient further agrees to insert similar provisions in all subcontracts or subgrants utilized in the performance of this grant.

K. Subcontractors or Subgrantees. The Subrecipient agrees that subcontractors or subgrantees will not be utilized in the performance of this Grant unless the Recipient has obtained prior written authorization for the use of subcontractors or subgrantees from the NHHSS.

L. Availability of Funding. Due to possible future reductions in State appropriations, the NHHSS cannot guarantee the continued availability of funding for this Subgrant notwithstanding the consideration stated above. In the event funds to finance this Subgrant become unavailable either in full or in part due to such reductions in appropriations, the NHHSS may terminate the Subgrant or reduce the consideration upon notice in writing to the Subrecipient. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery. The NHHSS shall be the final authority as to the availability of funds. The effective date of such Subgrant termination or reduction in consideration shall be specified in the notice as the date of service of said notice or the actual effective date of the funding reduction, whichever is later. Provided that reductions shall not apply to payments made for services satisfactorily completed prior to said effective date. In the event of a reduction in consideration, the Subrecipient may cancel this Subgrant as of the effective date of the proposed reduction upon provision of advance written notice to the NHHSS.

M. Access to Records and Audit Liability. All Subrecipient books, records, and documents relating to work performed or monies received under this Subgrant shall be subject to audit at any reasonable time upon the provision of reasonable notice by the NHHSS. These records shall be maintained for a period of six (6) full years from the date of final payment, or until all issues related to an audit, litigation or other action are resolved, whichever is longer. All records shall be maintained in accordance with generally accepted accounting practices.

In addition to, and in no way in limitation of any obligation in this Subgrant, the Subrecipient shall agree that it will be held liable for audit exceptions, and shall return to the NHHSS all payments made under this Subgrant for which an exception has been taken or which has been disallowed because of such an exception. The Subrecipient agrees to correct immediately any material weakness or condition reported to the NHHSS in the course of an audit.

N. Termination.

- 1) **Termination Due to Loss of Funds:** The NHHSS will terminate the Subgrant in full or in part, at the discretion of the NHHSS, in the event the NHHSS suffers a loss of the funding which permits it to fund this Subgrant. In the event the NHHSS suffers such a loss of funding, the NHHSS will give the Subgrantee written notice, which will set forth the effective date of full or partial termination, or if a change in funding is required, setting forth the change in funding and the changes in approved budget.
- 2) **Termination by Mutual Consent:** This Subgrant may be terminated in whole or in part, prior to the completion of the Subrecipient's project activities, when both parties agree that continuation is not feasible or would not produce beneficial results commensurate with the further expenditure of funds. The parties must agree on the termination conditions, including effective date and the portion to be terminated. The Subrecipient will not incur new obligations for the terminated portion after the effective date, and will cancel as many outstanding obligations as possible. If a release of funds has been achieved, the NHHSS will make funds available to the Subrecipient to pay for allowable expenses incurred before the effective date of termination.
- 3) **Termination for Cause:** In the event of a default or violation of the terms of this Subgrant by the Subrecipient or failure to use the Subgrant for only those purposes set forth, the NHHSS may take the following action:
 - (a) **Suspension** - After notice to the Subrecipient, suspend the Subgrant and withhold any further disbursement or prohibit the Subrecipient from incurring additional obligations of Subgrant funds, pending corrective action by the Subrecipient.
 - (b) **Termination** - Terminate the Subgrant in whole, or in part, at any time before the date of completion, whenever it is determined that the Subrecipient has failed to comply with the terms and conditions of the Subgrant. The NHHSS will promptly notify the Subrecipient in writing of the determination and the reasons for the termination, together with the effective date.

Payments made to the Subrecipient or recoveries by the NHSSR&L under this subsection, will be in accordance with the legal rights and liabilities of the parties.

Payments and recoveries may include, but are not limited to, payments allowed for costs determined to be not in compliance with the terms of this Subgrant up to the date of termination. The Subrecipient will return to the NHSSR&L all unencumbered funds. Further, any costs previously paid by the NHHSS which are subsequently determined to be unallowable through audit and close-out procedures may be recovered pursuant to subsection I(J) of these Terms and Assurances or deducted from future Subgrant awards.

- 4) **Recovery of Funds:** In the event of default, failure to complete the project, or violation of the terms of this Subgrant by the Subrecipient, the NHHSS may institute such action as necessary to reduce, withdraw, or recover all or part of the project funds from the Subrecipient.

Subrecipient Reporting Requirements

Report	Date Due	Date Submitted	Period Covered
Expenditure Report	The 20 th of the month following each two month payment period: July-Aug. due Sept. 20 Sept.-Oct. due Nov. 20 Nov. -Dec. due Jan. 20 Jan. -Feb. due March 20 March-April due May 20 May -June Due July 20		Previous two months
Community Education and Clinic Activity Reports	The 20 th of each month for the previous month activities.		Monthly
Board Meeting Minutes	Monthly or quarterly prior to the next Board meeting.		
(FPAR) OPA Title X FP/Program Data Report	Approximately January 25		January – December
Audit Report	Within 9 months of the end of the agency fiscal year or 30 days after the audit has been completed		Agency Fiscal Year
Narrative Progress Report of Title X Priorities	January		12 months
Revised Policies and Procedures	Throughout the year		
New Employee resumé	Following employment		

Attachment 6 Exhibit 2

**Program Specific Requirements
Nebraska Reproductive Health Program**

I. Compliance with Program Laws and Regulations Governing Title X Family Planning Grant

The Subrecipient agrees to provide all services pursuant to the DHHS BCHS Family Planning Guidelines; the Nebraska Reproductive Health Program Medical Policy and Procedure Manual and Administrative Policies and Procedures; Title X of the Public Health Services Act, 42 U.S.C. §300, et seq., Title X regulations, 42 CFR Part 59; Section 504 of Title V of the Social Security Act, 42 U.S.C. §704; and any amendments thereto issued during the term of the subgrant.

II. Compliance with Title V MCH Block Grant

The Subrecipient acknowledges that it may not use amounts paid to it for:

1. inpatient services, other than inpatient services provided to children with special health care needs or to high-risk pregnant women and infants and such other inpatient services as the secretary may approve;
2. cash payments to intended recipients of health services;
3. the purchase or improvement of land, the purchase, construction, or permanent improvement (other than minor remodeling) of any building or other facility, or the purchase of major medical equipment;
4. satisfying any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds;
5. providing funds for research or training to any entity other than a public or nonprofit private entity; or
6. payment for any item or service (other than an emergency item or service) furnished --
 - a. by an individual or entity during the period when such individual or entity is excluded from providing service under the Maternal and Child Health Act or Title XVIII (Medicare), Title XIX (Medicaid) or Title XX (Services for Families, Children, Aged or Disabled) of the Social Security Act pursuant to section 42 U.S.C. 1320a-7, 42 U.S.C. 1320a-7a, 42 U.S.C. 1320c-5, or 42 U.S.C. 1395u(j)(2) of the Social Security Act; or

- b. at the medical direction or on the prescription of a physician during the period when the physician is excluded from providing services in the Maternal and Child Health program or Title XVIII (Medicare), Title XIX (Medicaid) or Title XX (Services for Families, Children, Aged and Disabled) of the Social Security Act pursuant to 42 U.S.C. Section 1320a-7, 42 U.S.C. Section 1320a-7a, 42 U.S.C. Section 1320-5, or 42 U.S.C. 1395u(j)(2) of the Social Security Act and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

III. Payment: Title X and Title V Funds

- A. Allocation of Federal Funds. The Department shall provide funds to the Subrecipient to carry out its obligation under this subgrant. Federal funding shall be subject to the following conditions:
 - 1. Release of funds by the Department is contingent upon the Subrecipient providing non-federal funds as set forth in the award.
 - 2. No payments for the operation of the grant will be made in excess of funds awarded by the Department.
 - 3. Submission of a budget revision following notice of the award.
- B. Distribution of Funds. The Department shall distribute funds every other month or as otherwise agreed upon.
- C. Recovery of Funds. Funds may be recovered from a Subrecipient at any time the Department determines, based on Subrecipient reports of expenditures and operations, that the Subrecipient is not expending funds at a rate commensurate with the amount of funds distributed or provided for expenditures under the approved budget.
- D. Other Local Agencies. The Department reserves the right to fund more that one local agency to serve the same area or special population serviced by the Subrecipient, as long as more than one local agency is necessary to serve the full extent of need in that area of special population.
- E. Reduction in Funding. In the event the Department experiences funding shortages, the dollar amounts specified in the award may be reduced accordingly, and the Subrecipient may be required to reduce benefits to participants.
- F. Reservation of Right. The Department reserves the right to the following provisions:
 - 1. To reallocate funds among local agencies as needed to insure service to individuals at highest levels of priority.

2. To either terminate or curtail part of the activities in order to best utilize available funding in the event that all or part of the federal or state funds are withheld or are not forthcoming.
3. To suspend the Subrecipient's authority to obligate funds provided by the Department pursuant to this Subgrant pending corrective action by this Subrecipient or a decision to terminate this Subgrant.
4. To terminate immediately this Subgrant, in whole or in part when federal funding is terminated, suspended, not released or otherwise forthcoming.

Nebraska Health and Human Services System

Administrative and Audit Guidance

To recipients of state funds and subrecipients of federal funds: *An **independent certified public accountant (CPA)** licensed to practice in the state of Nebraska must prepare and issue **all types of reports**, i.e. review, audit or A-133 reports. **Audit or A-133 reports** for governmental organizations and not-for-profit organizations who receive federal payments are to be **prepared in accordance with Government Auditing Standards** as promulgated by the Comptroller General of the United States.*

Types of Organizations	Federal Authority	Cost Principles	YEAR-END FINANCIAL REPORTING Type of Report by Payment Threshold
Not-for-profit organizations	45 CFR Part 74	A-122	<ul style="list-style-type: none"> ▪ If state and federal payments from NHHSS are <i>less than \$75,000</i>, a <u>review report</u> is needed. ▪ If state and federal payments from NHHSS are <i>\$75,000 or greater</i>, an <u>audit report</u> is needed. ▪ If federal payments from all sources are <i>\$500,000 or greater</i>, <u>A-133 report</u> is needed.
College or University	45 CFR Part 74	A-21	<ul style="list-style-type: none"> ▪ If state and federal payments from NHHSS are <i>less than \$75,000</i>, a <u>review report</u> is needed. ▪ If state and federal payments from NHHSS are <i>\$75,000 or greater</i>, an <u>audit report</u> is needed. ▪ If federal payments from all sources are <i>\$500,000 or greater</i>, <u>A-133 report</u> is needed.
State, Local or Tribal Government	45 CFR Part 92	A-87	<ul style="list-style-type: none"> ▪ If state and federal payments from NHHSS are <i>less than \$75,000</i>, a <u>review report</u> is needed. ▪ If state and federal payments from NHHSS are <i>\$75,000 or greater</i>, an <u>audit report</u> is needed. ▪ If federal payments from all sources are <i>\$500,000 or greater</i>, <u>A-133 report</u> is needed.

AUDIT REQUIREMENT CERTIFICATION NEBRASKA HEALTH AND HUMAN SERVICES FINANCE & SUPPORT

Applicants receiving federal funds, directly or indirectly, must complete this certification. In Part I, *select either #1 or #2* as relevant to the applicant. An individual authorized by the applicant must **sign the Certification** in Part II. The Office of Management and Budget (OMB) Circular A-133 "Audits of States, Local Governments and Non-Profit Organizations" is referenced in this document as "OMB Circular A-133".

Applicant _____

NAME OF GRANT **TITLE X FAMILY PLANNING SERVICES AND TITLE V MCH GRANT**

CFDA* # **93.217 AND 93.994**

FTIN** _____

Applicant's Fiscal Year _____, 20__ to _____ 20__

* Catalog of Federal Domestic Assistance

** Federal Tax Identification Number

PART I

#1. [] As the applicant named above, *we will expend less than \$500,000* (for fiscal years ending after December 31, 2003) from all Federal Financial Assistance sources, not just the grant named above, and including commodities in our current fiscal year. **Therefore, we are not subject to the audit requirements of OMB Circular A-133.**

We are, however, responsible for engaging a Certified Public Accountant (CPA) licensed to practice in Nebraska to conduct and prepare either, a review or audit of our organization's financial statements and a report issued by the CPA. We acknowledge the audit must be completed no later than nine months after the end of our organization's current fiscal year. A copy of the report must be submitted to the Nebraska Health and Human Services Finance and Support address as shown at the end of Part I.

#2. [] As the applicant named above, *we will expend \$500,000 or more* (for fiscal years ending after December 31, 2003) from all Federal Financial Assistance sources, not just the grant named above, and including commodities in our current fiscal year. **Therefore we are subject to the single audit requirements of OMB Circular A-133.**

We will engage a certified public accountant (CPA) licensed to practice in Nebraska to conduct and prepare the audit of our organization's financial statements and components of the single audit pertaining to those financial statements. We acknowledge the audit must be completed no later than nine months after the end of our current fiscal year. **(#2 continued on next page)**

(#2 Continued)

We further acknowledge, that a single audit performed in accordance with OMB A-133 must be submitted to the Federal Audit Clearinghouse. The reporting package, as evidence the audit was completed, must contain:

- The recipient/subrecipient's financial statements,
- a schedule of Expenditure of Federal Awards,
- a Summary Schedule of Prior Audit Findings (if applicable),
- a corrective action plan (if applicable) and
- the auditor's report(s) which includes an opinion on this recipient/subrecipient's financial statements and Schedule of Expenditures of Federal Awards, a report on this recipient/subrecipient's internal control, a report on this recipient/subrecipient's compliance, and a Schedule of Findings and Questioned Costs.

We further acknowledge that the auditor and this recipient/subrecipient must complete and submit with the reporting package a Data Collection Form for Reporting on Audits of States, Local Governments and Non-Profit Organizations (SF-SAC).

We further acknowledge that a copy of this recipient/subrecipient's financial statements, auditor's report and SF-SAC must be submitted to Nebraska Health and Human Services Finance and Support and the Federal Audit Clearinghouse simultaneously. See the Federal Audit Clearinghouse webpage for its submission requirements:

<http://harvester.census.gov/sac/>

For NHHSS, send the audit to:

Nebraska Health and Human Services Finance and Support
Financial Services Division - Grants and Cost Management
P.O. Box 95026
Lincoln, NE 68509-5026

PART II

An individual authorized by the applicant must sign this Audit Certification:

I hereby certify the information furnished is correct to the best of my knowledge and belief and this subrecipient will comply with the requirements as stated in this certification.

Name and Title of Authorized Individual
(please print legibly or type)

Organization

Signature

Date

CERTIFICATION REGARDING LOBBYING

The undersigned certifies, to the best of his or her knowledge and belief that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, A Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, Disclosure Form to Report Lobbying in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Organization Name

Name and Title of Official Signing for Organization

Signature of Official / Date

CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable Federal funds in Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this certification, the applicant/subgrantee certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

Signature of authorized official signing on
behalf of applicant/subgrantee

Date

Organization

INSTRUCTIONS
FOR
CERTIFICATION REGARDING DEBARMENT,
SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION

1. By signing and submitting the proposal, the prospective lower tier participant is providing the certification set out below.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
4. The terms *covered transaction*, *debarred*, *suspended*, *ineligible*, *lower tier covered transaction*, *participant*, *person*, *primary covered transaction*, *principal*, *proposal*, and *voluntarily excluded*, as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
6. The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transaction," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded from Federal Procurement and Nonprocurement Programs.
8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

**CERTIFICATION REGARDING
DEBARMENT, SUSPENSION, INELIGIBILITY AND
VOLUNTARY EXCLUSION**

LOWER TIER COVERED TRANSACTIONS

<i>Before completing certification, read instructions on the previous pages.</i>
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1. The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.
2. Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Name and Title of Authorized Representative

Organization

Signature

Date

INSTRUCTIONS
for
Certification Regarding Drug-Free Workplace Requirements

1. By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.
2. The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free workplace Act.
3. For grantees other than individuals, Alternate I. applies.
4. For grantees who are individuals, Alternate II. applies.
5. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of the application, or upon award, if there is no application, the grantee must keep the identity of the workplaces(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.
6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios.)
7. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the changes(s), if it previously identified the workplaces in question (see paragraph five).
8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantee's attention is called in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. § 812) and as further defined by regulation (21 C.F.R. § 1308.11 through §1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant. Including: (i) All direct charge employees; (ii) all indirect charge employees unless their impact or involvement is insignificant to the performance of the grant; and (iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include worker not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS
 Alternate I. (Grantees Other Than Individuals)

<p><i>Before completing certification, read instructions on the previous pages.</i></p>
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1. The grantee certifies that it will or will continue to provide a drug-free workplace by:
 - a. Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
 - b. Establishing an ongoing drug-free awareness program to inform employees about –
 - (i) The dangers of drug abuse in the workplace;
 - (ii) The grantee's policy of maintaining a drug-free workplace;
 - (iii) Any available drug counseling, rehabilitation, and employee assistance programs; and
 - (iv) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
 - c. Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph a.;
 - d. Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—
 - (i) Abide by the terms of the statement; and
 - (ii) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace not later than five calendar days after such conviction;
 - e. Notifying the agency in writing within ten calendar days after receiving notice under paragraph d.(ii) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
 - f. Taking one of the following actions, within 30 calendar days of receiving notice under paragraph d.(ii), with respect to any employee who is so convicted—
 - (i) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended, or
 - (ii) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

- g. Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).
2. *The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:*

Place of Performance (street address, city, county, state, zip code)

☐ Check if there are workplaces on file that are not identified here.

Name and Title of Authorized Representative (Print)

Organization

Signature

Date

CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS
Alternate II. (Grantees Who Are Individuals)

1. The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity with the grant;
2. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

Name (Print)

Signature

Date

COVER SHEET
NEBRASKA DEPARTMENT OF HEALTH & HUMAN SERVICES
REGULATION & LICENSURE, OFFICE OF FAMILY HEALTH
TITLE X FAMILY PLANNING SERVICES
January 1, 2007 through June 30, 2008

Applicant Organization: _____

Area Proposing to Serve: _____

Federal Tax Identification Number: _____

Address: _____ **City/Zip:** _____

Phone Number: _____ **Fax:** _____

By submitting and signing this application, the applicant agrees that, if a subgrant is awarded, it will operate the program as described in the Subgrant Request for Proposal and in accordance with the Subgrant Terms and Assurances.

Name of Authorized Official (please print): _____

Signature of Authorized Official: _____

Title: _____

Date: _____

Catalog of Federal Domestic Assistance Numbers: 93.994 (Title V) & 93.217 (Title X)

Project Director or Contact person:

Name: _____

Title: _____

Address: _____

City/Zip: _____

Phone: _____

Fax: _____

E-mail: _____

Financial Officer:

Name: _____

Title: _____

Address: _____

City/Zip: _____

Phone: _____

Fax: _____

E-mail: _____

Budget Information

A. HHS R&L Funds Requested	Amount	Percentage (%)
1. Title X	\$ _____	_____
2. Title V	\$ _____	_____
B. Program Income	\$ _____	_____
C. In-Kind	\$ _____	_____
TOTAL PROGRAM BUDGET	\$ _____	100%

Program
Work Plan

PROJECT NAME: _____GOAL: # _____

Objective	Activities FY2007	Resources		Timeline Year <u>One</u>											
		People	Other	----- Q1 -----			----- Q2 -----			----- Q3 -----			----- Q4 -----		
				Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

This form addresses proposal requirements described in Section IIIB5 of the RFP.

- A. Describe your agency's experience in providing family planning and related reproductive health services. Include a description of existing licenses, certifications and permits related to carrying out these services.
- B. Describe your fiscal and administrative ability to administer grant funds. List previous grants, subgrants, or contracts received from State of Nebraska agencies in the past 5 years.
- C. What are the qualifications of key program staff? List and describe staff's previous experience with the types of activities to be conducted, including administration, clinical services, laboratory and pharmacy services, education, counseling and outreach. **Attach resumes.**

Attachment 9, page 2

- D. Describe your capacity to engage community partners in planning reproductive health services for low income persons.

- E. Describe the agency's ability to start up and begin implementation of the proposed services.

- F. Describe training needs for clinical services and fiscal management of the project.

- G. Describe the availability of clinic equipment, medical supplies, office furniture, computers, printers, copy machines, etc., to support staff and program needs.

BUDGET WORKSHEET
RFP for TITLE X FAMILY PLANNING SERVICES - Nebraska
January, 2007

COST CATEGORIES/ LINE ITEMS	BUDGET BY RESOURCE				TOTAL BUDGETED
	Title X	Title V	Program Income	In-kind	
Salaries (List positions/FTEs):					
Benefits					
Contracted Services (List):					
Supplies					
Travel					
Other					
Indirect Costs (Rate ___%; Attach copy of Indirect Cost Rate Agreement					
TOTALS					

Title X Family Planning Funding Formula

Definitions

For the purposes of this RFP and the funding formula, these definitions apply for clinic sites.

Primary Site - Largest, only, or lead clinical site for a delegate grantee. This may or may not be the center for the delegate's administrative functions. In some cases the administrative functions will exist with a parent organization while with independent non-profit delegates the administrative hub usually exists at the largest clinical site.

Class I Satellite - Open daily with a regular clinic schedule, permanent facility, but not the largest or lead clinic site.

Class 2 Satellite - Open for clinical services on a limited schedule, often termed "suitcase site".

Class 3 Satellite - Same as Class 2 only in communities with < 3000 population.

Delegate - a sub-recipient of Title X funding from the Grantee (NE-HHS R&L). The Grantee is identified by and funded directly from the Office of Population Affairs, U.S. Department of Health and Human Services through a competitive grant process.

Funding Formula

Step 1: A base allocation is made to a delegate agency based on the following amounts:

①	Primary Site	\$35,000 year
	Class 1 Satellite	\$14,000 year
	Class 2 Satellite	\$4,000 year
	Class 3 Satellite (population < 3000)	\$1,000 year

Step 2: Funds are further allocated based on the percent of unduplicated Low Income Women (LIW) users to Total Agency Users. The following scale represents the amounts given based on the percent determined:

% of LIW to Total Agency Users		
0 - 35%	=	\$0
36 - 45%	=	\$5,000 yearly
46 - 55%	=	\$10,000 yearly
56 - 65%	=	\$15,000 yearly
66 - 75%	=	\$20,000 yearly
76 - 85%	=	\$25,000 yearly
86 - 95%	=	\$30,000 yearly

Step 3: Using a computerized formula delegates are allocated funds based on: Number of unduplicated Low Income Women Users \leq 150% of poverty minus the Medicaid Users.

Step 4: Maternal Child Health (MCH) fund allocation is based on the percent of total allocable Title X funds that a delegate receives. For example, if an agency receives 10% of the total Federal Title X funds available through the funding formula they will receive 10% of the MCH funds available.